National Diabetes & Digestive & Kidney Diseases
Advisory Council Orientation Handbook

FEBRUARY 2009

NIDDK | NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

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NIH Gateway Center Map

Main Visitor Entrance: NIH Gateway Drive

Gateway Center - Building 66 (for pedestrians entering campus)

- Open 24 hours, 7 days a week

Gateway Inspection Station - Building 66A (for vehicles entering campus)

- Monday-Friday: 5am - 10pm
  Weekends: 6am - 6pm
- After inspection, vehicles enter campus at Center Drive
- Roadway at Center Drive is for entering campus only; visitors exiting campus may exit from other open locations.

Multi-Level Parking Garage 11 – MLP-11 (car inspection not required; visitor badges obtained at Gateway Visitor Center – Bldg 66) Hours: Monday - Friday: 6am – 9pm (entrance) 6am – 11pm (exit) Cost: $2 per hour for the first three hours, $12 maximum for entire day. Proceed to Visitors Center for personal inspection and pass.

Security Procedures for Entering the NIH Campus:

* All visitors and patients—**please be aware**: Federal law prohibits the following items on Federal property: firearms, explosives, archery equipment, dangerous weapons, knives with blades over 2 ½ inches, alcoholic beverages and open containers of alcohol.

* The NIH has implemented security measures to help ensure the safety of our patients, employees, guests and facilities. All visitors must enter through the **new** NIH Gateway Center and Visitor Center on Rockville Pike just south of the Metro station and previous visitor entrance at South Drive and Rockville Pike. **Except for persons parking in multi-level parking garage at the NIH Gateway Center (MLP-11)**, all vehicles entering the campus must submit to a vehicle inspection.

* Whether arriving by Metro, hotel shuttle, or private or commercial vehicle, visitors over 15 years of age must show one (1) form of a government-issued photo ID—driver's license, passport, green card, etc**.** Visitors under 16 years of age must be accompanied by an adult.

Tobacco-Free Campus: Effective October 1, 2008, the use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings; on all outside property or grounds, including parking areas; and in government vehicles.

Vehicle Inspections – Except for those parked in MLP-11, all vehicles and their contents will be inspected upon entering the campus. Additionally, all vehicles entering certain parking areas will be inspected, regardless of any prior inspection. Drivers will be required to present their driver's license and may be asked to open the trunk and hood. If you are physically unable to perform this function, please inform the inspector and they will assist you.

Vehicle inspection may consist of any combination of the following: Detection Dogs Teams (K-9), Electronic Detection Devices and Manual Inspection.

After inspection, you will be issued a vehicle inspection pass. It must be displayed on your vehicle's dashboard while you are on campus. The inspection pass is not a "parking permit." It only grants your vehicle access to enter the campus. You can only park in designated parking areas.

Personal Inspections – All visitors should be prepared to submit to a personal inspection prior to entering the campus. These inspections may be conducted with a handheld monitoring device, a metal detector and by visible inspection. Additionally, your personal belongings may be inspected and passed through an x-ray machine.

If driving onto campus, the personal inspection and issuance of a visitor badge will take place where your private or commercial vehicle (including a taxi) is inspected.

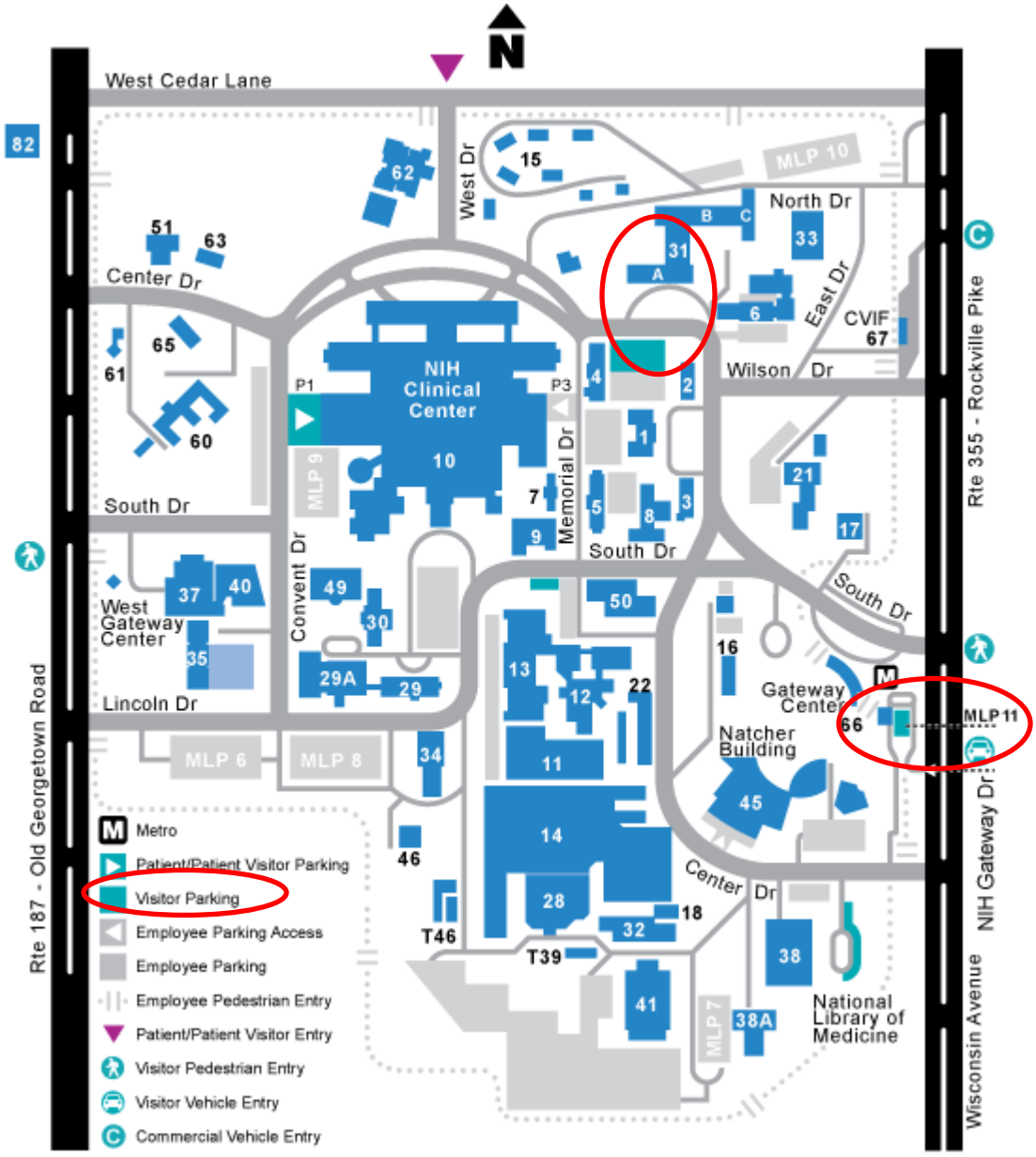
If you parked in the NIH Gateway Center multi-level garage (MPL-11), the personal inspection and issuance of a visitor badge will take place in the Visitor's Center. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://dtts.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp. Directional signs within Building 31 will guide you to the meeting room.

Visitor passes must be prominently displayed at all times while on the NIH campus.

To learn more about visitor and security issues at the NIH, visit: http://www.nih.gov/about/visitor/index.htm.

For questions about campus access, please contact the ORS Information Line at orsinfo@mail.nih.gov or 301-594-6677, TTY - 301-435-1908.

NIH Visitors Map of Campus



Street Address:
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

See Parking Information Below

General Visitor Parking Information

Parking:

Visitors may park at the **Gateway Parking Garage (MLP-11)** (see Gateway Center Map) or in designated visitor parking lots (see Campus Map):

Monday – Friday, 7am – 7pm:
$2.00 per hour for the first three hours
$12.00 for the entire day

Metered parking lots:
Monday – Friday, 7am – 7pm
$2 per hour

Arriving at NIH:

When traveling to the main NIH campus, use of the Metro is strongly encouraged. Visitor parking lots on the NIH campus fill up quickly.

If traveling via Metro or hotel shuttle to Medical Center Metro stop: The Washington D.C. Metro-Rail system Red Line has a station right on the NIH campus, called "Medical Center." Once you're out of the station, it's a short walk to the NIH Visitor Center where you will go through the NIH security procedures and receive a visitor's badge. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://dtts.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp. Directional signs within Building 31 will guide you to the meeting room

If taking a taxi directly to the meeting site: Upon entering the campus please let the driver know that you wish to be dropped off in front of Building 31. **The taxi must first go through an NIH security inspection of the car, and you and the driver must go through the security procedures and receive visitor badges**. Directional signs within Building 31 will guide you to the meeting room.

If driving private vehicle to the meeting site: Unless you choose to park in the NIH Gateway Center parking garage, receive your security processing at the Visitor Center, and take a shuttle to Building 31, you and your car must first go through security procedures. Visitor parking is located directly across from Building 31 (see **circles** on map). Parking fees are $12 per day and are fully reimbursable. Directional signs within Building 31 will guide you to the meeting room.

Vehicle and Visitor passes must be prominently displayed at all times while on the NIH campus.

System Map

MetroOpensDoors.com
Customer Information Service: 202/637-6000
TTY Phone: 202/638-3780

REV 10/27/06

No Smoking

No Eating or Drinking

No Animals (except service animals)

No Audio (without earphones)

No Litter or Spitting

No Dangerous or Flammable Items

Bethesda Area Map

For Information on the Bethesda Area: http://www.bethesda.org/bethesda/bethesda.htm

Glossary of Terms

For extensive list of grant terms see http://grants.nih.gov/grants/glossary.htm

A

Accession Number - Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Acquisition - Obtaining supplies or services by the Federal Government with appropriated funds through purchase or lease.

Active Grant - A grant meeting the following criteria: (1) Today's date is between the budget start and end dates; (2) The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Activity Code - A three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). *See* Funding Mechanisms in NIDDK section of Background Information.

Administrative Expenses – Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Administrative I/C - The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.

Administrative Supplement - Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Amendment (amended or revised applications) - Resubmission of an unfunded application revised in response to a prior review.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application - A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Identification Numbers - The application number identifies: type of application (1); activity code (R01); organization to which it is assigned (DK); serial number assigned by the Center for Scientific Review (CSR) (183723); suffix showing the support year for the grant (-01); other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. *See* Sample Application Number Graphical Overview of Grants Process.

Application Types – Type 1, New; Type 2, Competing continuation (a.k.a. renewal, re-competing); Type 3, Application for additional (supplemental) support; Type 4, Competing extension for an R37 award or first non-competing year of a Fast Track SBIR/STTR award; Type 5, Non-competing

continuation; Type 7. Change of grantee institution; Type 9, Change of NIH awarding Institute or Division (competing continuation.

Appropriation - Law authorizing Federal Agencies to obligate funds and make payments from the U.S. Treasury for specified purposes. Appropriations are in annual acts and permanent law.

Approved Budget - The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.

Award - The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Awarding Office - The NIH I/C responsible for the award, administration, and monitoring of particular grants.

B

Bilateral Agreement - A general science agreement between the U.S. and a foreign country. Grant applications from institutions in these countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Bridge Awards (R56) - Provides limited interim research support based on the merit of a pending R01 application while current researcher or new applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R56 with 1 year of funding, which the PI can choose to spend over a 2-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R56 mechanism. Interim funding ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Budget Appropriation - The yearly amount given to a Government Agency by Congress.

Budget Period - The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

C

Career Development Awards (CDA K Series) - Award supporting Ph.D.s and clinicians who wish to develop a career in biomedical research.

Capital Expenditure - The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may

be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds.

Clinical Research - Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual.

Clinical Trial - A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects); Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety; Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use; Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Close Out - Procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy; includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

Co-funding - Funding arrangement through which two or more Institutes or Centers pay for a grant.

Co-Investigator - An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS). Note: NIH does not recognize the term "co-PI."

Commitment Base - Funds used for non-competing (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Competing Applications - Either new or re-competing applications that must undergo initial peer review.

Competing Continuation - Application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)

Competitive Range - Contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.

Concept - The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts are brought before the Advisory Council for concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Conflict of Interest - Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement - Formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Constant Dollars - Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Contract (R&D) - Award instrument establishing a binding legal procurement relationship between NIH and a recipient obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute to pay for it.

Contracting Officer - Government employee authorized to execute contractual agreements on behalf of the Government.

Cooperative Agreement (U Series) - Support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Council/Board, Advisory - National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round - At NIH, there are typically three council rounds each fiscal year: September. January/February, and May/June. Application receipt dates, initial review dates, and council review dates all fall within one of these council rounds. Incoming grant applications all are assigned to a council round.

Critique - An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at a meeting.

Current Dollars - Actual dollars awarded, without adjustment for inflation.

D

Direct Costs - Costs that can be specifically identified with a particular project or activity.

Direct Operations - Funds for salary and other administrative costs.

Dual Assignments - Applications simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System - Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

DUNS Number - The Data Universal Numbering System (DUNS) number is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is recognized as the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in Commons.

E

Early Stage Investigator (ESI) – A New Investigator (*see* definition under N) who is within 10 years of completing a terminal research degree or within 10 years of completing medical residency. Between 1980 and 2001, the duration of postdoctoral training increased and the average age at which an investigator first obtained R01 funding increased by more than 5 years. Under the ESI program (NOT-OD-08-121 released September 26, 2008), New Investigators identified as ESIs will have their career stage considered at the time of review and award of R01 applications. By providing this advantage to ESIs, NIH can directly encourage earlier application for NIH research grant support. In some cases there may have been one or more lapses in the period of research or research training after the terminal degree or completion of medical residency. A new NIH Guide Notice (NOT-OD-09-034, released December 31, 2008, by the Office of Intramural Research) describes the procedures for requesting an extension of the ESI period and the conditions under which such extensions can be considered.

Electronic Research Administration (eRA) - NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required.

Enrollment Data - Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment - An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.

eRA Commons - A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required. At this site applicants access the status of their applications and grantees access the status of their awards, submit reports, and make requests electronically

Expiration Date - The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Research - Research supported by NIH to researchers and organizations outside the NIH through a grant, contract, or cooperative agreement

F

Facilities and Administrative Costs (F&A) - Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

Federal Acquisition Regulations (FAR) - Laws regulating government contracting.

Federal Advisory Committee Act (FACA) - A law regulating Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Register - An official, daily publication communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance.

Federal-Wide Assurance (FWA) - Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections—HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.

Fee - An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as “profit.”

Fellowship - An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.

Fiscal Year (FY) - The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2009 – Started October 1, 2008 and ends September 30, 2009.

Full-Time Appointment - Number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Funding Opportunity Announcement (FOA) – *See* Initiative.

G

Gender - Human subject term indicating a classification of research subjects into women and men.

Grant - Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals - A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Project Period - Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 2008 can be divided into competitive segments 2008 to 2012, 2012 to 2016, etc.

Grant Start Date - Official date a grant award begins; same as the first day of the first budget period.

Grantee - Organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Officer (GMO) - An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.

Grants Management Specialist (GMS) - An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

Grants.gov - An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (DHHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to http://www.grants.gov/.

H

High Risk/High Impact (HR/HI) - A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.

Human Subject - A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

Human Subjects Assurance - A document filed by an institution conducting research on human subjects with the Office for Human Research Protections—HHS that formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

I

Identifier - Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs - Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "Facility and Administrative Costs."

Information for Management, Planning, Analysis, and Coordination (IMPAC) - A computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

Informed Consent - Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Initial Peer Review Criteria – *Significance:* Is the topic important? Will it advance Scientific Knowledge? ***Approach:*** Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? ***Innovation:*** Does the proposal involve new ideas or methods; does it challenge existing paradigms? ***Investigator:*** Does the investigator and collaborators have the training and experience to do the work? ***Environment:*** Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations? Note: criteria-based scoring commences in 2009.

Initiative - A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not. *See* Funding Opportunity Announcement (FOA)

Institutional Base Salary - The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Institutional Review Board (IRB) - IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Interactive Research Project Grant (IRPG) - An award made to two or more investigators funded independently as R01 grantees but brought together as a collaborative group receiving additional support for collaborative work, shared resources, or the exchange of ideas.

Interagency Agreement - Formal agreement among Government agencies to collaborate on and fund research; Y series activity code.

Integrated Review Group (IRG) - A cluster of study sections responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.

Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SROs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO or GTA.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Investigational New Drug (IND) - Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research - Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research.

J

Just-In-Time - Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

K

Key Personnel - The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.

M

Matching or Cost Sharing - The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Mechanism – Another term for Activity Code.

MEDLINE - National Library of Medicine's database for scientific publications.

Minority Group - Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.

Model Organism - Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Modular Application - A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Monitoring - A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Multiple Principle Investigator - Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution.

N

New Application (award, grant) - Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.

New Investigator - New investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: Pathway to Independence Award-Research Phase (R00); Small Grant (R03); Academic Research Enhancement Award (R15); Exploratory/Developmental Grant (R21); Clinical Trial Planning Grant (R34); Dissertation Award (R36); Small Business Technology Transfer Grant-Phase I (R41); Small Business Innovation Research Grant-Phase I (R43); Shannon Award (R55); NIH High Priority, Short-Term Project Award (R56). Additionally, an individual is not excluded from consideration as a "New Investigator" if he/she has received an award from the following classes of awards: Training-Related and Mentored Career Awards; Fellowships (F05, F30, F31, F32, F34, F37, F38); Mentored-career awards (K01, K08, K22, K23, K25, K99-R00; Other mentored career awards (developmental K02 as used by NINDS and the developmental K07); Loan repayment contracts (L30, L32, L40, L50, L60). Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. *See* Early Stage Investigator.

Non-Competing Continuation - A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.

Non-Competing Grant - An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Notice of Award (NoA) - The legally binding document notifying the grantee and others that an award has been made. The NoA contains or references all terms and conditions of the award documenting the obligation of Federal funds and may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA).

Not Recommended for Further Consideration (NRFC) - A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review. The study section does not recommend funding; the application cannot be funded by an Institute.

O

Obligation - Data based on NIH funds that have been awarded by an NIH Institute/Center.

Office of Extramural Research (OER) - NIH office overseeing policies and guidelines for extramural research grants.

Office for Human Research Protections (OHRP) - HHS office overseeing human subject protection for HHS-supported research.

Office of Laboratory Animal Welfare (OLAW) - NIH office overseeing compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Office of Management and Budget (OMB) - Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants.

On Time - Paper applications using "standard" submission dates are on time if postmarked on or before the submission date. Electronic applications are on time if successfully submitted to Grants.gov by 5 p.m. local time on the date indicated. Note: For both paper and electronic submissions, when these dates fall on a weekend or holiday, they are extended to the next business day.

Organization - A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Organizational Code - A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. NIDDK's organizational code is DK.

Other Research Grants - Research grants not classified as research projects or research centers.

Other Support - Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

Overlap of Support - Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

P

Program Announcement Reviewed in an Institute (PAR) - Program Announcement with special receipt, referral and/or review considerations.

Parent Announcement - NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism [e.g., Research Project Grant (Parent R01)].

Payback - Time and effort fellows and T32 trainees must repay the Government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline - A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Peer Review - A system for evaluating research applications using reviewers who are the professional equals of the applicant.

Percentile - Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.

Person Months - Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Pre-application - A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

President's Budget - The annual budget request submitted to Congress by the U.S. President. The process begins with a budget request from the IC, which, as part of the entire NIH budget request, is modified by the Office of Management and Budget.

Principal Investigator - An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.

Prior Approval - Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds.

Priority score - A numerical rating that reflects the scientific merit of the proposed research relative to stated evaluation criteria.

Privacy Act - A law protecting against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs carrying out their missions through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA) - An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts.

Program Balance - The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Classification Code (PCC) - An internal code unique for each I/C indicating the I/C's scientific interest and used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

Program Official (PO) - The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

Programmatic Reduction - The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Number - Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Project Period - The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

Protocol - Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

PubMed - Provides access to citations from biomedical literature. It includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources. These citations are indexed with a PMID, a series of numbers.

R

Rating Criteria – *See* Initial Peer Review Criteria.

Real Property - Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Rebuttal - Procedure for contesting the peer review of a grant application. Synonymous with appeal.

Receipt, Referral, and Assignment of Applications - Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self assign.

Recipient - Organizational entity or individual receiving a grant or cooperative agreement. *See* Grantee.

Recommended - Designation given by a study section advising funding of an application. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support - Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Re-Competing - Grant whose term (e.g., 4years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.

Request for Application (RFA) - The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (RFP) - Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Research - A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”

Research Grants - Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs. Includes the following: R,P,M,S,K,U series (excluding UC6) DP1, DP2, D42, G12.

Research Misconduct - Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Portfolio - The cohort of grants supported by a given NIH organization.

Research Projects - Includes the following selected Research Grant and Cooperative Agreement activities: R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Project Grant (RPG) - Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. *See* Research Projects.

Research Supplement - Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Restriction - Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.

Resubmission - Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term was "revision." A resubmission has an entry in its application identification number (e.g., A1).

Review Cycle - Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review.

Revision - Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now “resubmission” in Grants.gov.

S

Salary Cap/Limitation - A legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

Scientific Overlap - Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Scientific Review Officer (SRO) - Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Scientific Review Group (SRG) - The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. Also known as Study Section.

Scored – In the peer review process, applications judged by a study section to be competitive (i.e., generally in the upper half of the applications reviewed). These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Selective Pay - The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Set-Aside - Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Signing Official (SO) – Person with has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Small Business Concern - A business independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its

affiliates, not more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

Small Business Innovation Research (SBIR) - A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs.

Small Business Technology Transfer (STTR) - A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs.

Special Emphasis – The NIDDK's policy to set aside funds that are used by the respective program divisions to fund meritorious grants whose competitive position places them beyond the established regular payline. It is the responsibility of the respective program divisions to identify such grants and through its established review procedures to determine which grants meet the Special Emphasis (SE) criteria and receive Subcouncil endorsement for funding. Each such application is then nominated for the Division Director's concurrence and approval by the Institute Director.

Specific Aims - A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).

Statement of Work (SOW) - In a contract proposal, the detailed description of the work to be performed under the contract.

Streamlined Non-Competing Award Process (SNAP) - Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP.

Streamlined Review (formerly Triage) - In the CSR peer review process, applications judged by a study section to be in the lower half of the applications evaluated in a given review round. These applications are generally not discussed during the study section meeting, but returned to the applicant with the assigned reviewers' written comments with no priority score. *See* Unscored.

Study Section - Panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called scientific review group (SRG) or initial review group (IRG).

Subaward - Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.

Success Rate – Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers.

NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.

Success Rate Base - The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Summary Statement - A combination of the reviewers' written comments and the Scientific Review Administrator's (SRA's) summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Supplement - A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3 application or award, a supplement can be either non-competing (administrative) or competing (subject to peer review).

T

Targeted Research - Research funded as a result of an Institute set-aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research.

Technology Transfer - Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local governments.

Terms and Conditions of Award - All legal requirements imposed on a grant by NIH, whether based on statue, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Tethered Application/Grant - When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the collaborative project. All applications are linked by a common project title and by cross-references within each application.

Total Project Costs – The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Training Awards - Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Translational Research - Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the

development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Triage – *See* Streamlined Review

Type – *See* Application Types.

U

Underrepresented Group - Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs.

Unscored - In the Center for Scientific Review peer review process, applications judged by a study section to be noncompetitive are generally in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed and applicants receive a summary statement. Between FY 1992 and FY 1995 the term "Not Recommended for Further Consideration" (NRFC) referred to noncompetitive applications.

V

Validation - The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

W

Withholding of Support - A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Book of NIH Abbreviations and Acronyms (2008)

Letter Codes Designating Funding for NIH Institutes, Centers in Grant Applications

Abbreviation	NIH Institutes, Centers	Letter Code Designating Funding Institute In Grant Applications
CC	Clinical Center*****	
CIT	Center for Information Technology*	
CSR	Center for Scientific Review*	
DS	Division of Safety, Office of Research Services*****	**DS**
FIC	John E. Fogarty International Center	**TW**
NCCAM	National Center for Complementary and Alternative Medicine	**AT**
NCCR	National Center for Research Resources	**RR**
NCI	National Cancer Institute	**CA**
NCMHD	National Center for Minority Health and Health Disparities	**MD**
NEI	National Eye Institute	**EY**
NHGRI	National Human Genome Research Institute	**HG**
NHLBI	National Heart, Lung, and Blood Institute	**HL**
NIA	National Institute on Aging	**AG**
NIAAA	National Institute on Alcohol Abuse and Alcoholism	**AA**
NIAID	National Institute of Allergy and Infectious Diseases	**AI**
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease	**AR**

*** Does Not Make Extramural Awards**

Abbreviation	NIH Institutes, Centers, Offices	Letter Code Designating Funding Institute In Grant Applications
NIBIB	National Institute of Biomedical Imaging and Bioengineering	**EB**
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	**HD**
NIDA	National Institute on Drug Abuse	**DA**
NIDCD	National Institute on Deafness and Other Communication Disorders	**DC**
NIDCR	National Institute of Dental and Craniofacial Research	**DE**
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	**DK**
NIEHS	National Institute on Environmental Health Sciences	**ES**
NIGMS	National Institute of General Medical Sciences	**GM**
NIH	Office of the Director	
NIMH	National Institute of Mental Health	**MH**
NINDS	National Institute on Neurological Disorders and Stroke	**NS**
NINR	National Institute of Nursing Research	**NR**
NLM	National Library of Medicine	**LM**
OD	Office of the Director	**OD**

Acronym	Definition
A	
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AAPHP	American Academy of Pediatrics
ABL	Applied BioScience Laboratories for Acquired Immunodeficiency Syndrome
ABRCMS	Annual Biomedical Research Conference for Minority Students
ABSL	American Bio-Safety Level
ACD	Advisory Committee to the Director
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families (DHHS)
ACGME	Accreditation Council for Graduate Medical Education
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society
ACS	American College of Surgeons
ACSI	American Customer Satisfaction Index
ACSR	AIDS and Cancer Specimen Resource, NCI
ACTG	AIDS Clinical Trials Group
ACTIS	AIDS Clinical Trials Information Service
ACTU	AIDS Clinical Trials Unit
ACUC	Animal Care and Use Committee
ADAMHA	Alcohol Drug Abuse and Mental Health Administration (now **SAMSHA**)
ADB	Automated Data Base System

ADB	Administrative Database System (NIH)
ADC	AIDS Dementia Complex
ADCR	Associate Director for Clinical Research
ADD	Attention Deficit Disorder
AdEERS	Adverse Event Expedited Reporting System
ADP	Automated Data Processing
ADR	Adverse Drug Reactions
ADR	Alternative Dispute Resolution
AE	Adverse Event
AER	Adverse Event Reporting
AFGE	American Federation of Government Employees
AFIP	Armed Forces Institute of Pathology
AFIP	Animal Facilities Improvement Program
AFL/CIO	American Federation of Labor/Congress of Industrial Organizations
AGEMAP	Atlas of Gene Expressions in Mouse Aging Project
AGRICOLA	AGRICultural OnLine Access
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AI	Amelogenesis Imperfecta
AI/ANO	American Indian/Alaskan Native Organization
AID	U.S. Agency for International Development
AIDS	Acquired Immunodeficiency Syndrome
AIDSinfo	HHS AIDS information Web site
AIEDRP	Acute Infection and Early Disease Research Program
AIRO	Agency Intramural Research Integrity Officer
AIRO	American Indian Research Opportunities

AITRC	Allergy, Immunology, and Transplantation Research Committee
AITRP	AIDS International Training and Research Program, FIC
AJCC	American Joint Committee on Cancer
AL	Annual Leave
ALAT	Assistant Laboratory Animal Technician (Certified by AALAS)
ALERT system	HHS system for disseminating information to Public Health Service officials about organizations or people charged with or found to have engaged in scientific misconduct (PHS)
AMA	American Medical Association
AMB	AIDS Malignancy Bank
AMC	AIDS Malignancy Consortium
AMC	Acquisition Management Committee
AMD	Age-related Macular Degeneration
AMHPS	Association of Minority Health Professionals Schools
AMIA	American Medical Informatics Association
AMLCD	Active matrix liquid crystal display
AMSSC	Administrative Management Systems Steering Committee
AMWG	AIDS Malignancies Work Group
ANL	Argonne National Laboratory, Argonne, IL
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AO	Administrative Official/ Administrative Office/ Administrative Officer
AOA	Administration on Aging
AP	Acquisition Plan
APA	Administrative Program Assistant
APAC	Annual Payback Activities Certification
APAO	Asian and Pacific Islander American Organization

APC	NIH Purchase Card Program Agency Program Coordinator
APD	Animal Program Director
APHA	American Public Health Association
APHIS	USDA - Animal and Plant Health Inspection Service
API	Application Programming Interfaces
APN	Advanced Practice Nursing
ARA	Awaiting Receipt of Application
ARAC	Administrative Restructuring Advisory Committee/Work Group on Acquisition
ARAC	AIDS Research Advisory Committee (NIAID)
ARB	Architecture Review Board
ARC	Administrative Resource Center
AREA	NIH Academic Research Enhancement Award (R15)
ARL	U.S. Army Research Laboratory
ARND	Alcohol-related Neurodevelopmental Disorder
ARRR	AIDS-Related Research Review
ARS	Agriculture Research Service
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	As Soon As Possible
ASB	Administrative Services Branch
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASDC	Administrative Skills Development Curriculum
ASH	Assistant Secretary for Health, PHS
ASI	Addiction Severity Index
ASP	Animal Study Proposal
ASPE	Office of the Assistant Secretary for Planning and Evaluation

ASPER	Assistant Secretary for Personnel Administration, DHHS
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
AT	Administrative Technician
ATCC	American Type Culture Collection, Manassas, VA
ATI	Analytic Treatment Interruption
ATIS	AIDS Treatment Information Service
ATPM	Association of Teachers and Preventive Medicine
ATSDR	Agency for Toxic Substances and Disease Registry
AVEG	AIDS Vaccine Evaluation Group
AVEU	AIDS Vaccine Evaluation Unit
AVRC	AIDS Vaccine Research Committee
AWA	Animal Welfare Act
AWOL	Absence Without Official Leave
AWS	AIDS-associated Wasting Syndrome
AZT	Zidovudine (generic name) or Azidothymidine

B

B&F	**Buildings and Facilities**
B&P	Bid and Proposal
B/Start	Behavioral Science Track Award for Rapid Transition
BAA	Broad Agency Announcement
BAFO	Best and Final Offer
BARC	Beltsville Agricultural Research Center
BBBP	Biobehavioral and Behavioral Processes
BC	Biomarker Consortium

BC/BS	Blue Cross/Blue Shield
BCP	Best Community Practice and Biophysical and Chemical Sciences
BCS	Biochemical Sciences
BDCN	Brain Disorders and Clinical Neuroscience
BDP	Biopharmaceutical Development Program
BDR	Budget Data Request
BEA	Bureau of Economic Analysis
BECON	Bioengineering Consortium (NIH OD)
BEMIS	Biomaterials and Medical Implant Science
BEP	Bureau of Engraving and Printing
BESA	Border Epidemiologic Study of Aging
BEST	Biomonitoring of Environmental Status and Trends
BFRL	Building and Fire Research Laboratory
BGCRG	Breast and Gynecologic Cancer Research Group
BHPr	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BIC	Business Information Center
BIG	Blacks in government
BIGR	Biomaterials and Information for Genomic Research™ ((Ardais Corporation)
BIMAS	Bioinformatics Molecular Analysis Section
BIO	Biotechnology Industry Organization
BIRADS	Breast Imaging Reporting and Data System
BIRN	Biomedical Informatics Research Network
BIS	Bureau of Industry and Security
BISM	Blind Industries and Services of Maryland
BISTI	Biomedical Information Science and Technology Initiative

BISTIC	Bioinformatics Consortium (NIH OD)
BITS	Business Information Technology System
BJA	Bureau of Justice Assistance
BJS	Bureau of Justice Statistics
BL-3	Biosafety Level 3
BLA	Biologics License Application
BLIRC	Biomedical Library and Informatics Review Committee
BLM	Bureau of Land Management
BLS	Board on Life Sciences
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMDO	Ballistic Missile Defense Organization
BML	Biological Material License
BMMR	Biological Models and Materials Research
BMO	Business Management Office
BNA	Bureau of National Affairs
BNL	Brookhaven National Laboratory, Upton, NY (Department of Energy Organization)
BOA	Basic Ordering Agreement
BOG	Board of Governors, NIH
BOP	Federal Bureau of Prisons
BOR	Board of Regents
BOR	Bureau of Reclamation
BoS	Board of Survey
BPA	Blanket Purchase Agreement
BPD	Bureau of Public Debt
BPH	Benign Prostatic Hyperplasia

BPHC	Bureau of Primary Health Care
BPSRG	Basic Prevention Science Research Group
BRB	Benefits Review Board
BRCA	Breast Cancer
BRD	Biological Resource Division,
BRDPI	Biomedical Research and Development Price Index, measures real annual changes in the prices of items and services required for research and development (R&D) activities
BRFSS	Behavioral Risk Factor Surveillance System
BRG	Biometry Research Group
BRIN	Biomedical Research Infrastructure Network
BRMP	Biological Response Modifiers Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
BSC	Business Service Centers
BSI	Brief Symptom Inventory
BSL	Bio-Safety Level
BSSC	Behavioral and Social Sciences Coordinating Committee
BTP	Biotechnology Training Program
BTR	Biomedical Technology Resource
BTS	Bureau of Transportation Statistics
BVA	Board of Veterans Appeals

C

CAM	Complementary and Alternative Medicine
CBER	Center for Biologics Evaluation and Research
CBIAC	Chemical and Biological Defense Information Analysis Center

CBO	Congressional Budget Office
CBT	Computer-Based Training
CC	Warren Grant Magnuson Clinical Center, NIH
CCB	Configuration Control Board
CCB	Child Care Bureau
CCC	Commodity Credit Corporation
CCO	Chief Contracting Officer
CCR	Center for Career Resources (OD)
CCR	Center for Cooperative Resolution
CCR	Commission on Civil Rights
CCSS	Childhood Cancer Survivor Study
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation
CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDBG	Community Development Block Grants
CDC	Centers for Disease Control and Prevention, PHS (Public Health Service)
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research
CDFI	Community Development Financial Institutions
CDHR	Center for Devices and Radiological Health
CDMC	Central Data Management Center
CDMRP	Congressionally Directed Medical Research Program
cDNA	Complementary DNA
CDs	Communication Directors
CES	Central E-mail Service
CDP	Career Development Plan

CDR	Clinical Drug Request
CDUS	Clinical Data Update System
CDW	Consultant Days Worked
CEA	Council of Economic Advisers
CEC	Contractor Establishment Code
CEDR	Comprehensive Epidemiologic Data Resource
CEGS	Centers of Excellence in Genomic Science
CEL	Commercial Evaluation License
CEN	Bureau of the Census
CEPPO	Chemical Emergency Preparedness and Prevention Office
CEPS	Center for Earth and Planetary Studies
CEQ	Council on Environmental Quality
CERCLIS	Comprehensive Environmental Response, Compensation, & Liability Information System
CETEC	Topographic Engineering Center
CF	Consent Form
CFAR	Centers for AIDS Research
CFC	Combined Federal Campaign
CFDA	Catalog of Federal Domestic Assistance, a database that helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the database called the "CFDA number."
CFO	Chief Financial Office
CFOC	Chief Financial Officers Council
CFR	Code of Federal Regulations
CFS CRC	Chronic Fatigue Syndrome Cooperative Research Centers
CFSAN	National Center for Food Safety and Applied Nutrition
CGAP	Competitive Grant Application Process
CGH	Comparative genomic hybridization

CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CHB	Community Health Branch (DOHS)
CHID	Combined Health Information Database
ChiMP	NIH Chimpanzee Management Program
CHIMP	Chimpanzee Health, Improvement, Maintenance and Protection Act
CHTN	Cooperative Human Tissue Network
CIAO	Critical Infrastructure Assurance Office
CIC	Consumer Information Center
CID	Center of Infectious Diseases (CDC)
CIDI	Composite International Diagnostic Interview (Clinical Trials Standard)
CIO	Chief Information Officer
CIPRA	Comprehensive International Program for Research on AIDS
CIS	Cancer Information Service
CISET	Committee on International Sciences, Engineering, and Technology
CIT	Center for Information Technology
CJD	Creutzfeldt-Jakob Disease
CLC	Community Liaison Council
CLIA	Clinical Laboratories Improvement Act
CLM	Council of Logistics Management
CMAB	Complaints Management and Adjudication Branch (OEO)
CMAP	Cancer Molecular Analysis Project
CMB	Comparative Medicine Branch
CMBD	Collection Management & Delivery Branch (DLS)
CME	Continuing Medical Education
CMHS	Center for Mental Health Services
CML	Chronic Myeloid Leukemia

CMO	Committee Management Officer, IC person responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act; responsible for developing committee charter, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures, etc.
CMP	Contract Management Program
CMP/HMO	Comprehensive Medical Plans/Health Maintenance Organizations
CMPP	Center for Nutrition Policy and Promotion
CMS	Centers for Medicare and Medicaid Services
CMSP	Cooperative Medical Sciences Program
CMV	Center for Minority Veterans
CNCRIT	Collaborative Network for Clinical Research on Immune Tolerance
CNS	Central Nervous System
CO	Contracting Officer
COB	Close of Business
COBRE	Centers of Biomedical Research Excellence
CoC	Commission on Cancer
CoC	Council of Councils
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COGA	Collaborative Study on the Genetics of Alcoholism
COI	Conflict of Interest
COLA	Cost of Living Allowance
CONSER	Cooperative Online Serials
COOG	Continuity of Operations Group
COOP	Continuity of Operations Plan
COP	Continuation of Pay
COP	Costal Ocean Program

COPR	Council of Public Representatives (serves NIH Director)
COPS	Office of Community Oriented Policing Services
COPTRG	Community Oncology and Prevention Trials
COR	Career Opportunities in Research Education and Training
COSEPUP	Committee on Science Engineering and Public Policy
COTA	Career Opportunities Training Agreement (HHS)
COTS	Commercial Off-The-Shelf Software Products
CPA	Cooperative Project Assurance
CPAF	Cost Plus Award Fee
CPDF	Central Personnel Data File
CPE	Continuing Professional Education
CPFP	Cancer Prevention Fellowship Program
CPI	Consumer Price Index
CPIF	Cost Plus Incentive Fee
CPMS	Defense Civilian Personnel Management Service
CPO	Corrections Program Office
CPS	Contractor Performance System
CPS	Center for Prevention Services (CDC)
CPSC	Consumer Product Safety Commission
CR	Continuing Resolution
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRC	Civil Rights Center
CRC	New Clinical Research Center
CRF	Case Report Form (Source Document for Clinical Studies)

CRIB	Central Institutional review Board
CRIC	Chronic Renal Insufficiency Cohort
CRIS	Clinical Research Information System
CRISP	Computer Retrieval of Information on Scientific Programs, A searchable biomedical database of federally supported proposed research conducted at universities, hospitals, institutions, etc.
CRL	Charles River Laboratories
CRM	Customer Relations Manager
CRO	Contract Research Organization
CRP	Conference Room Pilot
CRP	Conservation Reserve Program
CRS	Congressional Research Service
CRS	Clinical Research Scholar
CRS	Community Relations Service
CRTA	Cancer Research Training Award
CRTP	Clinical Research Training Program
CRVP	Clinical Research Volunteer Program
CS	Contract Specialist
CSAC	Central Services Advisory Committee
CSAP	Center for Substance Abuse Prevention
CSAT	Center for Substance Abuse Treatment
CSB	Customer Service Branch (DMAPS)
CSB	Chemical Safety and Hazard Investigation Board
CSD	Client Services Division
CSE	Office of Child Support Enforcement
CSI	Center for the Study of Intelligence
CSR	Center for Scientific Review

CSREES	Cooperative State Research, Education, and Extension Service
CT	Computed Tomography
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTC	Common Toxicity Criteria
CTEP	Clinical Therapeutic Evaluation Program
CTEP	Cancer Therapy Evaluation Program
CTN	National Drug Abuse Treatment Clinical Trials Network
CTP	Community Treatment Program
CTSA	Clinical and Translational Science Awards
CTSU	Clinical Trials Support Unit
CU	Coordinating Unit
CUAP	College and University Affiliations Program
Cumulus SPMS	Cumulus Slide/Presentation Management System
CVS	Cardiovascular Sciences
CVS	Chorionic Villus Sampling
CWC	Chemical Weapons Convention
CWD	Chronic Wasting Disease
CY	Calendar Year

D

D&A	Design and Analysis Workgroup
D&B	Dun & Bradstreet Number
DAP	Division of Acquisition Programs, OLAO
DARPA	Defense Advanced Research Projects Agency
DASAM	Deputy Secretary for Administration and Management

DASPA	Division of Advanced Studies and Policy Analysis
DB	Design Branch (DMAPS)
DBASSE	Division of Behavioral and Social Sciences and Education
DBBD	Division of Biological Basis of Disease
DBDR	Division of Blood Diseases and Resources
DBPS	Division of Bioengineering and Physical Science
DBT	Division of Biomedical Technology
DCA	Division of Cost Allocation
DCAA	Defense Contract Audit Agency
DCCT	Diabetes Control and Complications Trial
DCIS	Department Contract Information System
DCLG	Director's Consumer Liaison Group
DCM	Division of Comparative Medicine
DCMC	Defense Contract Management Command
DCMS	Division of Mail and Courier Services (ORS)
DCPS	Division of Clinical and Population Based Studies
DCR	Division of Career Resources, OHRM, NIH
DCR	Division of Clinical Research
DCRT	Division of Computer Research and Technology (now CIT)
DDC	Defense Distribution Center
DDER	Deputy Director of Extramural Research, NIH
DDIR	Deputy Director for Intramural Research
DDKR	Drug Delivery & Kinetics Resource (DBPS)
DDM	Deputy Director for Management
DDN	Division of Digestive Diseases and Nutrition, NIDDK
DDP	Diamminedichloroplatinum

DEA	Division of Extramural Activities, NIDDK
DEC	Deputy Ethics Counselor
DeCA	Defense Commissary Agency
DEIS	Division of Extramural Information Systems
DELPRO	Delegated Procurement System
DEM	Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
DEMS	Division of Events Management Services (PES or P&ES)
DEPC	Division of Emergency Preparedness & Coordination
DEPS	Division of Epidemiology and Population Studies
DERT	Division of Extramural Research and Training
DES	Division of Engineering Services
DFAS	Defense Finance and Accounting Service (sends out DHHS/NIH W2s for honorariums, etc.)
DFM	Division of Financial Management
DHHS	Department of Health and Human Services
DHRS	Division of Human Resource Systems, OHRM, NIH
DHVD	Division of Heart and Vascular Diseases
DICOM	Digital Imaging and Communications in Medicine
DINFOS	Defense Information School
DIR	Division of Intramural Research, NIDDK
DITA	Division of Information Technology Acquisition, OLAO (also know as NITAAC)
DITR	Division of International Training and Research
DLD	Division of Lung Diseases
DLS	Division of Library Services
DLS	Division of Logistics Services, OLAO
DLT	Digital linear tape
DM	Data management

DMAPS	Division of Medical Arts and Printing Services
DMAS	Data Management and Analysis Subcommittee
DMCM	Division of Molecular and Cellular Mechanisms
DMCS	Division of Mail and Courier Services
DMDC	Defense Manpower Data Center
DMID	Division of Microbiology and Infectious Diseases
DMS	Division of Management Services
DNA	Deoxyribonucleic Acid
DOHS	Division of Occupational Health and Safety
DORRA	DLA Office of Operations Research and Resource Analysis
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPPS	Division of Personal Property Services, OLAO
DPS	Division of Physiological Systems
DPSM	Division of Physical Security Management
DRA	Division of Research Acquisition, OLAO
DRI	Division of Research Infrastructure
DRR	Division of Receipt and Referral
DRS	Division of Radiation Safety
DRSB	Diagnostic & Research Services Branch
DS	Division of Safety
DSEIS	Division of Scientific Equipment and Instrumentation Services (ORS)
DSFM	Division of Space and Facility Management
DSMB	Data and Safety Monitoring Board
DSM-IV	Diagnostic & Statistical Manual of Mental Disorders – 4th Edition
DSO	Division of Security Operations
DSS	Division of Support Services

DSSA	Division of Station Support Acquisition, OLAO
DTIC	Defense Technical Information Center
DTM	Department of Transfusion Medicine (ORS)
DTP	Developmental Therapeutics Program
DTTS	Division of Travel and Transportation Services
DUNS	Data Universal Numbering System
DVR	Division of Veterinary Resources
DW	Data Warehouse
DWD	Division of Workforce Development

E

EA	Expanded Authorities
EA	Enterprise Architecture
EAC	External Advisory Committee
EACC	External Affairs Coordinating committee
EAP	Employee Assistance Program
EBSA	Employee Benefits Security Administration
EC	Executive Committee
EC	European Commission
ECA	Executive Committee for Acquisition
ECA	Bureau of Educational and Cultural Affairs
ECAB	Employees' Compensation Appeals Board
ECB	Electronic Council Book
ECFMG	Educational Commission for Foreign Medical School Graduates
ECIE	Executive council on Integrity and Efficiency
ECL	Executive Committee on Logistics

ECOSOC	Economic and Social Council
ECP	Emergency Conservation Program
ECR-LRP	Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
EDGAR	Electronic Data Gathering, Analysis, and Retrieval
EDI	Electronic Data Interchange
EDIC	Epidemiologic Cohort Study
Edison	Extramural Invention Information Management System
EDRG	Early Detection Research Group
EDRN	Early Detection Research Network
EEO	Equal Employment Opportunity
EEOC	Equal Employment Opportunity Commission
EES	Enterprise E-Mail System
EHP	Environmental Health Perspectives
EHRP	Enterprise Human resources and Payroll System
EIA	Energy Information Administration
EIN	Entity Identification Number
EIR	Employee Invention Report
EIS	Epidemic Intelligence Service
ELS	Earnings and Leave Statement
ELSI	Ethical, Legal and Societal Implications
EL-TRAINS	Electronic Logistics Training & Support Network
EM	Office of Environmental Management
EML	Environmental Measurement Laboratory
EMPSB	Events Management Program Support Branch (DEMS)
ENC	Eisenhower National Clearinghouse
ENR	Endocrinology and Reproductive Sciences

ENS	Early Notification System
EO	Executive Order
EOB	Editorial Operations Branch
EOC	Ethics Oversight Committee
EOD	Entrance on Duty
EOIR	Executive Office for Immigration Review
EOP	Executive Office of the President
EOUSA	Executive Office for United States Attorneys
EP	Extramural Programs
EPMC	Extramural Program Management Committee
EPN	Executive Plaza North (6130 Executive Blvd.; Rockville, MD 20852)
EPRU	Enteric Pathogens research Unit
EPS	Executive Plaza South(6120 Executive Blvd.; Rockville, MD, 20852)
EPSCoR	Experimental Program to Stimulate Competitive Research
EPSS	Electronic Performance Support Systems
eRA	Electronic Research Administration
ERDA	Energy Research and Development Administration
EREN	Energy Efficiency and Renewable Energy Network
ERIC	Educational Resources Information Center
EROD	Educational Resource Organizations Directory
ERP	Extramural Research Program
ERS	Economic Research Service
ERSB	Equipment Rental & Sakes Branch (DSEIS)
ES	Executive Secretariat (NIH)
ESA	Extramural Scientist Administrator
ESA	Employment Standards Administration

ESA	Economics and Statistics Administration
ESDIM	Environmental Services Data and Information Management
ESG	Executive Staffing Group (REPS, PMB, NCI)
eSNAP	Electronic Streamlined Non-competing Award Process
ETA	Employment and Training Administration
ETSO	Employee Transportation Services Office

F

F & A	Facilities and Administrative Cost
F Awards	Fellowship Awards
FACA	Federal Advisory Committee Act
FAES	Foundation for Advanced Education in the Sciences
FAI	Fair Act Inventory
FAIR Act	Federal Activities Inventory Reform Act
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FARB	Funding Advisory Review Board
FASAB	Federal Accounting Standards Advisory Board
FASEB	Federation of American Societies for Experimental Biology
FCC	Federal Communications Commission
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration (PHS)
FDP	Federal Demonstration Partnership
FECA	Federal Employees' Compensation Act
FEGLI	Federal Employees' Group Life Insurance
FEHBP	Federal Employees' Health Benefit Program

FEMA	Federal Emergency Management Agency
FERC	Federal Energy Regulatory Commission
FERS	Federal Employees' Retirement System
FFLA	Family Friendly Leave Act
FIC	John E. Fogarty International Center
FICA	Federal Insurance Contributions Act (Social Security)
FIRST	First Independent Research Support and Transition Award
fMRI	Functional Magnetic Resonance Imaging
FMS	Financial Management Service
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act of 1966, amended 1986
FRB	Federal Reserve Board
FRS	Federal Reserve System
FTC	Federal Trade Commission
FTE	Full Time Equivalent
FTTP	Full-Time Training Position
FWA	Federal Wide Assurance
FY	Fiscal Year (October 1 – September 30)
FYI	For Your Information

G

GAO	General Accounting Office, Congress
GBV-C	Hepatitis G (GB Virus-C)
GCRC	General Clinical Research Center
GDB	Human Genome Database
GH	Growth Hormone

GM	Grants Management
GMB	Grants Management Branch Office
GME	Graduate Medical Education
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPA	Grade Point Average
GPEA	Government Paperwork Elimination Act of 1998
GPO	Government Printing Office
GPRA	Government Performance Results Act of 1993
GPS	Global Positioning Satellite System
GRE	Graduate Record Examinations
GS	General Schedule
GSA	General Services Administration
GTA	Grants Technical Assistant
GWAC	Government-Wide Acquisition Contract

H

HAART	Highly Active Antiretroviral Therapy
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HDR-LRP	Loan Repayment Program for Health Disparities Research
HEM	Hematology Study Section
hESC	Human Embryonic Stem Cells
HHMI	Howard Hughes Medical Institute
HHS	Health and Human Services (Department of)

HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HPV	Human Papillomavirus
HQ	Headquarters
HRSA	Health Resources and Services Administration, PHS
HRT	Hormone Replacement Therapy
HSA	Health Scientist Administrator
HSRAC	Human Subjects Research Advisory Committee
HSRB	Human Subjects Review Board
HSV	Herpes Simplex Virus
HTML	Hypertext Markup Language

I

IACUC	Institutional Animal Care and Use Committee
IAG	Interagency Agreement
IAR	Internet Assisted Review
IBC	Institutional Biosafety Committee
IC	Institute and Center (NIH)
ICC	Interstate Commerce Commission
ICD	Institutes/Centers/Divisions
ICF	Informed Consent Form
ID	Identification
IDE	Investigational Device Exemption (FDA)
IDeA	Institutional Development Award Program (NCRR)
IDIQ	Indefinite Delivery Indefinite Quality Contract

IDM	Infectious Diseases and Microbiology
iEdison	NIH's Extramural Electronic Invention Reporting system
IFCN	Integrative, Functional and Cognitive Neuroscience
IG	Inspector General
IHS	Indian Health Service, PHS
IMA	Internal Monitoring Board
IMAGE	Integrated Molecular Analysis of Genomes and their Expression
IMF	International Monetary Fund
IMPAC	Integrated Management, Planning, Analysis and Coordination (Data System)
IMPAC II	Information for Management, Planning, Analysis, and Coordination
IMS/ADB	Information Management System/Administrative Data Base System (DELPRO)
IND	Investigational New Drug Application (FDA)
INS	Immigration and Naturalization Service (now the United States Citizenship and Immigration Services)
IO	Information Officer
IOM	Institute of Medicine, NAS
IP	Intellectual Property
IPC	Incidental Patient Contact
IPF	Institutional Profile File Number
IRA	Individual Retirement Account
IRACDA	Institutional Research and Academic Career Development Award
IRB	Institutional Review Board
IRG	Integrated Review Group, a cluster of study sections responsible for review of grant applications in scientifically related areas; sections share common intellectual and human resources.
IRM	Information Resources Management
IRP	NIH Intramural Research Program
IRPG	Interactive Research Project Grant

IRTA	Intramural Research Training Award or Agreement
ISO	International Organization for Standardization
ISSO	Information Systems Security Office
IT	Information Technology
ITAS	Integrated Time and Attendance System
ITB	Information Technology Branch
ITC	United States International Trade Commission

J

JAX	The Jackson Laboratory
JHU	Johns Hopkins University
JOFOC	Justification for Other than Full and Open Competition
Just-in-time	Grant application timeframe that requires applicants to send some information to NIH only if an award is likely. Also used for other support information, and other items, including: certification of IRB approval, Federal wide assurance, IACU certification, and letter stating key personnel have been trained in protecting human subjects

K

K Awards	Mentored and Career Development Awards
KSA	Knowledge, Skills and Ability Form
KSASF	Knowledges, Skills, Abilities Supplemental Form (NIH-2252-3)
KUH	Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

L

LABS	Laboratory Automated Bibliographic System
LAN	Local Area Network

LAO	Leave Approving Official
LAS	Laboratory Animal Sciences
LAT	Laboratory Animal Technician (AALAS Certified)
LATG	Laboratory Animal Technologist (AAALAS Certified)
LCM	Laser Capture Microdissection
LI	Lead Investigator
LOC	Library of Congress
LOCIS	Library of Congress Information System
LOE	Level of Effort
LOI	Letter of Intent
LRP	Loan Repayment Program (NIH)
LWOP	Leave Without Pay

M

MA	Master Agreement
MAC	Multiple Award Contract
MACs	Multiple Agency Contracts
MARC	Minority Access to Research Career Program
MBRS	Minority Biomedical Research Support
MC	Manual Chapter
MCDN	Molecular, Cellular and Developmental Neuroscience
MCP	NIH Management Cadre Program
MCR	Management Control Review
MCSB	Mail Customer Service Branch (DMCS)
MCRU	Metabolic Clinical Research Unit (in NIH Clinical Center)
MEDLINE/ PUBMED	National Library of Medicine’s Database for Scientific Publications

MEO	Most Efficient Organization
MERIT	Method to Extend Research in Time Award
MeSH	Medical Subject Headings
MF	NIH Management Fund
MHC	Major Histocompatibility Complex
MHPF	Minority Health Professionals Foundation
MI	Minority Institutions
MIGA	Multilateral Investment Guarantee Agency
MIS	Medical Information System
ML	Military Leave
MM	Medical Monitor
MODY	Maturity Onset Diabetes of the Young
MORE	Minority Opportunities in Research
MOU	Memorandum of Understanding
MOU/MOA	Memorandum of Understanding/Memorandum of Agreement
MPA	Multiple Project Assurance
MPP	Merit Program Plan (NIH)
MPW	Medical Pathological Waste
MRA	Minimum Retirement Age
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
M-RISP	Minority-Research Infrastructure Support Program
mRNA	Messenger RNA
MRS	Magnetic Resonance Spectroscopy
MSDS	Material Safety Data Sheet
MSPB	Merit Systems Protection Board

MTA	Material Transfer Agreement
MTCT	Mother-to-Child Transmission

N

N/A	Not Applicable/Not Available
NAFTA	North American Free Trade Agreement
NAHFE	National Association of Hispanic Federal Executives
NARA	National Archives and Records Administration
NARCH	Native American Research Centers for Health
NARFE	National Association of Retired Federal employees
NAS	National Academy of Sciences (U.S.)
NBAC	National Bioethics Advisory Commission
NBII	National Biological Information Infrastructure
NBN	National Biospecimen Network
NBRSS	NIH Business and Research Support System
NBS	New Business Systems/NIH Business System
NCBI	National Center for Biotechnology Information
NCC	National Coordinating Center for Telecommunications
NCCAM	National Center for Complementary and Alternative Medicine (NIH)
NCCDPHP	National Center for Chronic Disease and Prevention Health Promotion (CDC)
NCCIC	National Child Care Information Center
NCCLS	National Committee for Clinical Laboratory Standards
NCD	National Council on Disability
NCEH	National Center for Environmental Health (CDC)
NCES	National Center for Education Statistics
NCHS	National Center for Health Statistics

NCI	National Cancer Institute (NIH)
NCICAS	National Cooperative Inner-City Asthma Study
NCIPC	National Center for Injury Prevention and Control (CDC)
NCMHD	National Center on Minority Health and Health Disparities (NIH)
NCRR	National Center for Research Resources (NIH)
NCSDR	National Center on Sleep Disorders Research
NCTR	National Center for Toxicological Research
NCUA	National Credit Union Administration
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDDKDAC	National Diabetes and Digestive and Kidney Diseases Advisory Council
NDIC	National Drug Intelligence Center
NDRI	National Disease Research Interchange
NED	NIH Enterprise Directory
NEI	National Eye Institute (NIH)
NFT	Notification of Foreign Travel
NGA	Notice of Grant Award
NGO	Non-Government Organization
NHGRI	National Human Genome Research Institute (NIH)
NHIC	National Health Information Center
NHLBI	National Heart, Lung, and Blood Institute (NIH)
NHP	Nonhuman Primate
NHRPAC	National Human Research Protection Advisory Committee
NHSC	National Health Sciences Scholarship
NIA	National Institute on Aging (NIH)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (NIH)

NIAID	National Institute of Allergy and Infectious Disease (NIH)
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH)
NIBIB	National Institute of Biomedical Imaging and Bioengineering (NIH)
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDCD	National Institute on Deafness and Other Communication Disorders (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIH DW	NIH Data Warehouse
NIHAC	The National Institutes of Health Animal Center (Poolesville, MD)
NIHITS	NIH Integrated Training System
NIHTC	National Institutes of Health Training Center
NIMH	National Institute of Mental Health (NIH)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
NINR	National Institute of Nursing Research (NIH)
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIST	National Institute of Standards and Technology
NLAES	National Longitudinal Alcohol Epidemiologic Survey
NLM	National Library of Medicine (NIH)
NLT	Not Later Than
NMA	National Medical Association
NMR	Nuclear Magnetic Resonance

NMS	Nutritional and Metabolic Sciences
NOA	Nature of Action
NOGA	Notice of Grant Award
Non-FTE	Non Full-time Equivalent
NOTA	National Organ Transplant Act
NPEBC	National Programs of Excellence in Biomedical Computing
NPRC	National Primate Research Center
NREN	National Research and Education Network
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRFC	Not Recommended for Further Consideration
NRL	Naval Research Laboratory
NRSA	National Research Service Award (e.g., T32, F32)
NS	No Score (lower 50% of grants in study section)
NSF	National Science Foundation
NSRG	Nutritional Science Research Group
NSTC	National Science and Technology Center
NSTL	National Space Technology Laboratories
NTE	Not To Exceed
NTIA	National Telecommunications and Information Administration
NTIS	National Technical Information Service
NTP	National Toxicology Program

O

OA	Office of Administration
OACU	Office of Animal Care and Use
OAM	Office of Administrative Management (OD)

OAMP	Office of Acquisition Management and Policy, OA
OAPP	Office of Adolescent Pregnancy Programs (OASH)
OAR	Office of AIDS Research
OASDI	Old Age Survivor Disability Insurance
OASH	Office of the Assistant Secretary for Health, PHS
OASPA	Office of the Assistant Secretary for Public Affairs
OB	Office of Budget (NIH OD)
OBA	Office of Biotechnology Activities (NIH OD)
OBL	Office of Business Liaison
OBSF	Office of Business Systems & Finance (OD)
OBSSR	Office of Behavioral and Social Sciences Research (NIH OD)
OC	Office of Communications
OCAB	Office of the Assistant Secretary for Health, PHS
OCC	Operations Coordinating Committee
OCCC	Office of Clinical Center Communications
OCL	Office of Community Liaison (NIH OD)
OCPL	Office of Communications & Public Liaison
OD	Office of the Director, NIH
ODA	Official Duty Activities
ODEO	Office of the Director Executive Office (NIH OD)
ODEP	Office of Disability Employment Policy
ODP	Office of Disease Prevention (NIH OD)
ODS	Office of Dietary Supplements (NIH OD)
OE	Office of Education (NIH OD)
OEEO	Office of Equal Employment Opportunity (NIH OD)
OEO	Office of Equal Opportunity

OEODM	Office of Equality, Opportunity & Diversity Management
OEP	Office of Extramural Programs, OER, OD, NIH
OER	Office of Extramural Research, OD, NIH
OFACP	Office of Federal Advisory Committee Policy (NIH OD)
OFCCP	Office of Federal Contract Compliance Programs
OFM	Office of Financial Management
OFRM	Office of Financial Resources Management
OGC	Office of the General Counsel (NIH OD)
OGE	Office of Government Ethics
OHASIS	Office of Health and Safety Information System
OHER	Office of Health and Environmental Research
OHR	Office of Human Resources (NIH OD)
OHRM	Office of Human Resource Management (NIH OD)
OHRP	Office for Human Research Protections
OHS	Office of Healthy Start (HRSA)
OHSR	Office of Human Subjects Research
OIB	Office of Information Branch
OIG	Office of the Inspector General (USDA)
OIIA	Office of Intergovernmental and Interagency Affairs
OIR	Office of Intramural Research (NIH OD)
OIT	Office of Information Technology
OLAO	Office of Logistics and Acquisition Operations
OLAW	Office of Laboratory Animal Welfare, OER, OD, NIH
OLM	Office of Logistics Management
OLPA	Office of Legislative Policy and Analysis (NIH OD)
OLRS	Office of Loan Repayment and Scholarship (NIH OD)

OM	Office of Management (NIH OD)
OMA	Office of Management Assessment (NIH OD)
OMAR	Office of Medical Applications of Research (NIH OD)
OMB	Office of Management and Budget (White House)
OMBS	Office of Medical Board Services
OMH	Office of Minority Health (OASH)
OMS	Occupational Medical Services (DOHS)
ONC	Oncological Sciences
OPASI	Office of Portfolio Analysis and Strategic Initiatives (dissolved October 2008)
OPDIV	Operating Division (HHS)
OPEC	Office of Prevention, Education, and Control
OPERA	Office of Policy for Extramural Research Administration
OPF	Official Personnel File
OPHS	Office of Public Health and Science
OPL	Offices of Public Liaison (NIH OD)
OPM	Office of Personnel Management
OPRR	Office of Protection from Research Risks
ORA	Office of Reports and Analysis, OER, OD, NIH
ORD	Office of Rare Diseases (NIH OD)
ORI	Office of Research Integrity, HHS
ORIM	Office of Information Resources Management
ORS	Office of Research Services
ORWH	Office of Research on Women's Health, OD, NIH
OS	Office of the Secretary
OSA	Office of Scientific Affairs, OER, OD, NIH
OSC	Office of Strategic Coordination, DPCPSI, OD, NIH

OSD	Office of the Scientific Director
OSE	Office of Science Education (NIH OD)
OSHA	Occupational Safety and Health Administration
OSHRC	Occupational Safety and Health Review Commission
OSMP	Office of Strategic Management and Planning (NIH OD)
OSP	Office of Science Policy (NIH OD)
OSPA	Office of Science Policy Analysis
OSPP	Office of Science Policy and Planning
OST	Office of Science and Technology
OSTI	Office of Scientific and Technical Information
OSTP	Office of Science and Technology Policy (White House)
OT	Overtime
OTA	Office of Technology Assessment
OTD	Office of Technology Development
OTS	Omega Travel Service (NIH Travel Agent)
OTT	Office of Technology Transfer
OUTPT	Outpatient
OWH	Office on Women's Health

P

P/TRP	Promotion/Tenure Review Panel
PA	Program Announcement
PA	Purchasing Agent
PAM	Office of Acquisition and Property Management
PAR	Program Announcement with special receipt or review
PART	Program Assessment Rating Tool (OMB)

PAS	Program Announcement with Set-aside funds
PCA	Physicians Comparability Allowance
PCBE	President's Council on Bioethics
PD	Position Description
PDF	Portable Document Format
PET	Positron Emission Tomography
PETA	People for the Ethical Treatment of Animals
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (U.S.)
PHS OWH	U.S. Public Health Service's Office on Women's Health
PHTN	Public Health Training Network
PI	Principal Investigator
PIA	Procurement Integrity Act
PIN	Personal Identification Number
PKU	Phenylketonuria
PLC	Program Leadership Committee
PMI	Presidential Management Intern
PMIS	Property Management Information System
PMO	Property Management Officer
PO	Program Official
PO	Project Officer (For a Grant or Contract)
PO	Purchase Order
Post-Doc	Post-Doctoral Fellow
PP	Pay Period
PPE	Pay Period Ending
PPP	Public Private Partnerships

PPS	Pathophysiological Sciences
PR	Public Relations
PRB	Protocol Review Board
PRC	Processing Resource Centers
Pre-Doc	Pre-Doctoral Fellow
PRG	Progress Review Groups
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Project EXPORT	Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training
PROTRACK	Clinical Center Protocol Tracking Database
PrP	Prion Protein
PRPL	Patient Recruitment and Public Liaison Office
PRRR	Program Review Report Record
PRS	Protocol Review Subcommittee
PSC	Program Support Center
PSC	Publications Subcommittee
PSO	Professional Service Order
PSP	Physician Special Pay (Title 38)
PTSD	Post-Traumatic Stress Disorder
PWS	Performance Work Statement

Q

Q&A	Questions and Answers
QA	Quality Assurance
QALY	Quality-Adjusted Life Years
QAP	Quality Assurance Program

QAS	Quality Assurance Subcommittee
QC	Quality Control
QRB	Quality Review Board
QSI	Quality Step Increase

R

R&D	Research & Development
R&W	Recreation and Welfare
R01	Standard NIH Research Project Grant
R34	Investigator-Initiated Clinical Trial Planning and Implementation Grants
R56	Grant allowing an interim award so principal investigator can continue while reapplying for an R01 grant. Also enables new investigators to gather preliminary data to improve their grant applications. (Bridge Award)
RA	Research Assistant
RAC	Recombinant-DNA Advisory Committee
RAID	Rapid Access to Intervention Development
RAL	Restored Annual Leave
RALAT	Registered Assistant Laboratory Animal Technician
RAO	Regulatory Affairs Officer
RCC	Research Coordination Council (Department-wide)
RCDA	Research Career Development Award (K-series awards)
RCDC	Research, Condition, and Disease Categorization
RCR	Responsible Conduct of Research
RCRII	RCMI Clinical Research Infrastructure Initiative
RCT	Randomized Controlled Trial
rDNA	Recombinant DNA
RFA	Request for Application (request for grant applications for a research area)

RFC	Request For Contract
RFI	Request for Information
RFIP	Research Facilities Improvement Program
RFP	Request For Proposal (request for contract proposal for a project)
RFQ	Request for Quotation
RIF	Reduction In Force
RIMS	Robocom Inventory Management System
RISE	Research Initiative for Scientific Enhancement
RM	Roadmap
RMA	Risk Management Agency
RMS	Research Management Support
RNA	Ribonucleic Acid
RNAi	RNA interference
RPC	Review Policy Committee
RPG	Research Project Grant
RPHB	Risk, Prevention, and Health Behaviors
RRTC	Regional Research and Training Center
RSA	Rehabilitation Services Administration
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSOB	Radiation Safety Operations Branch (DRS)
RSUM	Research Supplements for Underrepresented Minorities

S

SAC	Simplified Acquisition Committee
SAE	Serious Adverse Event

SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SB	Small Business
SBA	U.S. Small Business Administration
SBIR	Small Business Innovation Research
SBO	Small Business Office
SBRS	Senior Biomedical Research Service
SBS	Small Business Specialist
SBSA	Small Business Set-Aside
SC	Steering Committee
SCD	Service Computation Date
SCORE	Support of Continuous Research Excellence
SD	Scientific Director
SDB	Small Disadvantaged Business
SEER	Surveillance, Epidemiology, and End Results
SE	Special Emphasis
SEP	Special Emphasis Panel (an SRG convened for a single meeting)
SES	Senior Executive Service
SF	Standard Form
SF	Staff Fellow
SIG	Shared Instrumentation Grant
SIMS	Scientific Initiative Management System
SIP	Summer Internship Program in Biomedical Research
SLA	Simple Letter of Agreement
SMSA	Small Business & Minority Business Set Aside
SNAP	Streamlined Noncompeting Award Process
SNEM	Social Science, Nursing, Epidemiology, and Methods

SNMA	Student National Medical Association
SNOMED	Systemized Nomenclature of Medicine
SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
SNPs	Single Nucleotide Polymorphisms
SO	Signing Official
SOP	Standard Operating Procedure
SOW	Statement Of Work
SPA	Single Project Assurance
SPF	Specific-pathogen free
SPIN	Shared Pathology Informatics Network
SPORE	Specialized Program of Research Excellence
SRAs	Scientific Review Administrator (an NIH scientist administrator in charge of review and advisory groups; now called SROs)
SRB	Surgery, Radiology, and Bioengineering
SRB	Scientific Review Board
SREA	Scientific Review Evaluation Awards
SRFP	Summer Research Fellowship Program
SRG	Scientific Review Group (performs initial scientific merit review of grant application & contract proposals; also called Initial Review Group (IRG) when pertaining to grant applications)

SROs	Scientific Review Officer (manages the peer review process for grant applications and contract proposals; designated Federal official responsible for the peer review meeting; major focus is on scientific rather than administrative activities; former title was SRO)
SSB	Support Services Branch (DP)
SSEB	Source Selection Evaluation Board
SSF	Senior Staff Fellow
SSF	Service and Supply Fund
SSN	Social Security Number
SSS	Special Study Section
STD	Sexually Transmitted Disease
STDCRC	Sexually transmitted Disease Cooperative Research Centers
STDCTU	Sexually Transmitted Disease Clinical Trials Unit
STEP	Staff Training in Extramural Programs
STI	Scientific and Technical Information
STTR	Small Business Technology Transfer
SV	Student, or Special Volunteer

T

T&A	Time and Attendance
TAIMS	Time and Attendance Information Management System
TEHIP	Toxicology and Environmental Health Program
TIA	Time Off Incentive Award
TIG	Time In Grade
TIN	Payer Identification Number Tax
TK	Timekeeper
TMA	Tissue Microarray
TMJ	Temporomandibular joint

TO	Task Order
TOD	Tour of Duty
TOXNET	Toxicology Data Network
TQM	Total Quality Management
TSC	Training Subcommittee
TSP	Thrift Savings Plan
TTB	Technology Transfer Branch
TX	Treatment

U

U.S.C.	United States Code
UMLS	Unified Medical Language System
URC	User Resource Center
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USIA	United States Information Agency
USOPM	United States Office of Personnel Management
USUHS	Uniformed Services University of Health Sciences

V

VA	Veterans Administration
VA	Department of Veterans Affairs
VF	Visiting Fellow
VLTP	Voluntary Leave Transfer Program
VRC	Vaccine Research Center

VRP	Veterinary Resources Program
VS	Visiting Scientist
VSOF	Visual Status of Funds

W

WAG	Widely Attended Gathering
WFCL	Work and Family Life Center
WG	Wage Grade
WGI	Within-Grade Increase
WHI	Women's Health Initiative
WHO	World Health Organization, United Nations
WTO	World Trade Organization
WWW	World Wide Web
WYLBUR	Interactive system providing simultaneous service to more than 825 terminals or microcomputers.

X

X-Train	Trainee Activities System

Y

YTD	Year To Date

Z

ZIP (Code)	Zone Improvement Plan

National Institute of Diabetes and Digestive and Kidney Diseases Mission and History

From 1950 until May 19, 1972, the Institute was known as the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, it was the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, it was the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports research on many of the most serious diseases affecting public health. The Institute supports much of the clinical research on the diseases of internal medicine and related subspecialty fields, as well as many basic science disciplines.

The Institute's Division of Intramural Research encompasses the broad spectrum of metabolic diseases such as diabetes, obesity, inborn errors of metabolism, endocrine disorders, mineral metabolism, digestive and liver diseases, nutrition, urology and renal disease, and hematology. Basic research studies include biochemistry, biophysics, nutrition, pathology, histochemistry, bioorganic chemistry, physical chemistry, chemical and molecular biology, and pharmacology.

NIDDK extramural research is organized into four divisions: Diabetes, Endocrinology, and Metabolic Diseases; Digestive Diseases and Nutrition; Kidney, Urologic, and Hematologic Diseases; and Extramural Activities.

The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, and career development and training awards. The Institute also supports research and development projects and large-scale clinical trials through contracts.

Important Events in NIDDK History

August 15, 1950—President Harry S. Truman signed the Omnibus Medical Research Act into law establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine Institute and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases.

November 15, 1950—The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

November 22, 1950—U.S. Surgeon General Leonard Scheele established NIAMD.

1959—Dr. Arthur Kornberg, former chief of the Institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

The Institute initiated an intramural research program in gastroenterology and launched an intramural research program in cystic fibrosis with the establishment of the Pediatric Metabolism Branch.

1961—Laboratory-equipped, mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1969—The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute, who reported his celebrated partial cracking of the genetic code while an NIAMD scientist (1957-1962).

November 1970—The Institute celebrated its 20th anniversary. U.S. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, as well as past and present Institute National Advisory Council members.

May 19, 1972—The Institute name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases.

October 1972—Christian B. Anfinsen, chief of the Institute's Laboratory of Chemical Biology, shared a Nobel Prize with 2 other American scientists for his demonstration of one of the most important simplifying concepts of molecular biology, that the 3-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of this research cited by the award was performed while with NIH.

September 1973—The Institute's diabetes centers program was initiated with the establishment of the first Diabetes-Endocrinology Research Centers.

November 1975—After 9 months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the *Long-Range Plan to Combat Diabetes*, to Congress. Recommendations encompassed expansion and coordination of diabetes and related research programs; creation of a diabetes research and training centers program; acceleration of efforts in diabetes health care, education, and control programs; and establishment of a National Diabetes Advisory Board.

April 1976—After a year of study and public hearings, the National Commission on Arthritis and Related Musculoskeletal Diseases issued *The Arthritis Plan*—its report to Congress. The report called for increased arthritis research and training programs, multipurpose arthritis centers, epidemiologic studies and data systems in arthritis, a National Arthritis Information Service, and a National Arthritis Advisory Board.

October 1976—Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the Institute. This advance has proven to be a scientific and clinical landmark in detection and control of viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977—The NIH Director established a trans-NIH program for diabetes, with lead responsibility in NIAMDD.

September 1977—Over $5 million in grants was awarded to 5 institutions to establish Diabetes Research and Training Centers.

October 1977—In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the Institute to collect, analyze, and disseminate data on this disorder to scientific and public health policy and planning associations.

December 1977—Institute grantees Dr. Roger C.L. Guillemin and Dr. Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist, Dr. Rosalyn S. Yalow. Guillemin and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

December 1978—A study of cystic fibrosis focused on the need for future research activities, including increased support for clinical and basic research, expansion of specialized cystic fibrosis research resources, emphasis on training of scientific personnel, and coordination of public and private cystic fibrosis research activities.

January 1979—Following 2 years of study and public hearings, the National Commission on Digestive Diseases issued its report, *The National Long-Range Plan to Combat Digestive Diseases.* Recommendations to Congress included the establishment of a National Digestive Diseases Advisory Board, an information clearinghouse, and increased emphasis on educational programs in digestive diseases in medical schools.

December 1979—A task force completed its study and submitted the report, *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases.*

September 1980—Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at NIH to be named to the distinguished executive rank in the Senior Executive Service. President Jimmy Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980—NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease," and dinner at the National Naval Medical Center. Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

June 23, 1981—The Institute was renamed National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

April 1982—U.S. Department of Health and Human Services (HHS) Secretary Richard S. Schweiker elevated NIADDK's programs to division status, creating 5 extramural divisions and the Division of Intramural Research.

November 1982—Dr. Elizabeth Neufeld received a Lasker Foundation Award. She is cited, along with Dr. Roscoe E. Brady of NINCDS, for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984—Grants totaling more than $4 million were awarded to 6 institutions to establish Silvio O. Conte Digestive Disease Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986—The Institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases.

June 3, 1986—The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

August 1, 1987—Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December 25, 1987—In response to congressional language on the FY 1988 appropriation for the NIDDK, the institute established a program of cystic fibrosis research centers.

September 16, 1990—NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June, 1991—The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature.

September 30, 1992—Three Obesity/Nutrition Research Centers and an animal models core to breed genetically obese rats for obesity and diabetes research were established.

October 12, 1992—Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." They have received grant support from NIDDK since 1955 and 1956, respectively.

October 30, 1992—In response to congressional language on the Institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993—The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to NIDDK.

October 10, 1994—Dr. Martin Rodbell and Dr. Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher in the National Institute of Arthritis and Metabolic Diseases, now NIDDK.

June 22, 1997—Led by NIDDK, NIH and the U.S. Centers for Disease Control and Prevention (CDC) announce the National Diabetes Education Program (NDEP) at the American Diabetes Association annual meeting in Boston. The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease, and its complications.

June 2000—In an effort to reduce the disproportionate burden of many diseases in minority populations, NIDDK initiated an Office of Minority Health Research Coordination.

November 16, 2000—NIDDK celebrated its 50th Anniversary. Professional societies in 8 U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. "A New Century of Science. A New Era of Hope" was published to highlight research supported and conducted by NIDDK and concluded the year with a joint scientific symposium at the Society for Cell Biology's 40th Anniversary meeting in December.

June 13, 2003—To avoid confusion with the newly-established NIH Obesity Research Task Force, NIDDK changed the name of its National Task Force on Prevention and Treatment of Obesity, established in 1991, to the Clinical Obesity Research Panel (CORP).

June 2003—The *Report on Progress and Opportunities: Special Statutory Funding for Type 1 Diabetes Research* described recent achievements and major projects that address unmet research needs in type 1 diabetes. From fiscal year 1998 through fiscal year 2008, the special funding program provides a total of $1.14 billion in research funds to supplement other funds for type 1 diabetes research provided through the regular appropriations process.

January 2005—The trans-NIH *Action Plan for Liver Disease Research*, a comprehensive plan that addresses the burden of liver diseases in the United States and maps out challenges for future research was released. The *Action Plan* was developed under the guidance of NIDDK's Liver Disease Research Branch.

September 2005—The NIH Director established the National Commission on Digestive Diseases to develop a long-range plan to improve the health of the Nation through digestive diseases research for submittal to the NIH Director and to Congress. NIDDK was selected as the lead agency to oversee this endeavor.

October 2006— *Advances and Emerging Opportunities in Type 1 Diabetes Research: A Strategic Plan* developed under the leadership of NIDDK was released by NIH. The strategic plan identifies goals and objectives to exploit recent scientific advances in combating this autoimmune form of diabetes.

April 2007—Griffin P. Rodgers, M.D., M.A.C.P., was appointed the ninth Director of NIDDK.

February 2008—NIDDK developed and released the Awareness and Prevention Series of new health information to raise awareness about diabetes, digestive diseases, and kidney and urologic diseases among people not yet diagnosed with these illnesses. The fact sheets (in English or Spanish) are for use at community health fairs, workplace health forums, family reunions, and other similar events.

NIDDK Legislative Chronology

December 11, 1947—Under section 202 of Public Law 78-410, the Experimental Biology and Medicine Institute was established.

August 15, 1950—P.L. 81-692, the Omnibus Medical Research Act, authorized establishment of NIAMDD to "... conduct researches relating to the cause, prevention, and methods of diagnosis and treatment of arthritis and rheumatism and other metabolic diseases, to assist and foster such researches and other activities by public and private agencies, and promote the coordination of all such researches, and to provide training in matters relating to such diseases...." Section 431 also authorized the U.S. Surgeon General to establish a national advisory council.

May 19, 1972—President Richard M. Nixon signed P.L. 92-305 to bring renewed emphasis to research in digestive diseases by changing the name of the Institute to NIAMDD and by designating a digestive diseases committee within the Institute's National Advisory Council.

August 29, 1972—The National Cooley's Anemia Control Act (PL 92-414) authorized research in the diagnosis, treatment, and prevention of this debilitating inherited disease, also known as thalassemia, occurring largely in populations of Mediterranean and Southeastern Asian origin.

July 23, 1974—P.L. 93-354, the National Diabetes Mellitus Research and Education Act, was signed. The National Commission on Diabetes, called for by this act, was chartered on September 17, 1974. Members were appointed by the Secretary of the U.S. Department of Health, Education and Welfare (HEW) . The Act called for centers for research and training in diabetes and establishment of an intergovernmental diabetes coordinating committee, including NIAMDD and 6 other NIH institutes.

January 1975—The National Arthritis Act of 1974 (P.L. 93-640) was signed into law to further research, education, and training in the field of the connective tissue diseases. The HEW Secretary appointed the mandated National Commission on Arthritis and Related Musculoskeletal Diseases, June 2. The Act required centers for research and training in arthritis and rheumatic diseases and the establishment of a data bank, as well as an overall plan to investigate the epidemiology, etiology, control, and prevention of these disorders.

October 1976—P.L. 94-562, the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, established the National Diabetes Advisory Board charged with advising Congress and the HEW Secretary on implementation of the "Long-Range Plan to Combat Diabetes," developed by the National Commission on Diabetes. The law also established the National Commission on Digestive Diseases to deal with many problems, including investigation into the incidence, duration, mortality rates, and social and economic impact of digestive diseases.

The National Arthritis Advisory Board, established by the same law, reviews and evaluates the implementation of the *Arthritis Plan*, formulated by the Arthritis Act of 1974. The board advises

Congress, the HHS Secretary, and heads of Federal agencies with respect to the plan and other Federal programs relating to arthritis.

December 1980—Title II of the Health Programs Extension Act of 1980, P.L. 96-538, changed the Institute's name to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. The Act also established the National Digestive Diseases Advisory Board. The law authorized the National Diabetes Information Clearinghouse, the Diabetes Data Group, and the National Digestive Diseases Information and Education Clearinghouse. In addition, it reauthorized advisory boards for arthritis and diabetes research.

November 20, 1985—The Health Research Extension Act of 1985, P.L. 99-158, changed the Institute name to the National Institute of Diabetes and Digestive and Kidney Diseases. The act also established the National Kidney and Urologic Diseases Advisory Board. The law gave parallel special authorities to all Institute operating divisions, including authorization of the National Kidney and Urologic Diseases Information Clearinghouse; National Kidney, Urologic, and Hematologic Diseases Coordinating Committee; National Kidney and Urologic Diseases Data System; National Digestive Diseases Data System; kidney and urologic diseases research centers; and digestive diseases research centers.

June 10, 1993—The NIH Revitalization Act of 1993, P.L. 103-43, established NIDDK as the lead institute in nutritional disorders and obesity, including the formation of a research and training centers program on nutritional disorders and obesity.

It also provided for the directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Aging, National Institute of Dental Research, and the NIDDK to expand and intensify programs with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

July 25, 1997—A House report accompanying H.R. 2264 and Senate report with S. 1061, FY 1998 appropriations bills for Labor/HHS/Education, urged NIH and NIDDK to establish a diabetes research working group to develop a comprehensive plan for NIH-funded diabetes research that would recommend future initiatives and directions. Dr. C. Ronald Kahn, diabetes research working group chairman, presented "Conquering Diabetes, A Strategic Plan for the 21st Century" to the Congress on March 23, 1999.

August 1997—The Balanced Budget Act of 1997 (P.L. 105-33) established a *Special Statutory Funding Program for Type 1 Diabetes Research* . The program provided $30 million per year for fiscal years 1998 through 2002. This funding program augmented regularly appropriated funds that HHS received for diabetes research through the Labor-HHS-Education Appropriations Committees. The NIDDK, through authority granted by the HHS Secretary, has a leadership role in planning, implementing, and evaluating the allocation of these funds.

October 17, 2000—The "Children's Health Act of 2000 (P.L. 106-310) amended the Public Health Service Act with respect to children's health. Title IV, entitled "Reducing Burden of Diabetes Among Children and Youth," section 402, specified that NIH conduct long-term epidemiology studies, support regional clinical research centers, and provide a national prevention effort relative to type 1 diabetes.

December 2000—The Fiscal Year 2001 Consolidated Appropriations Act (P.L. 106-554) extended and augmented the Special Statutory Funding Program for Type 1 Diabetes Research in amount and time, allocating an additional $70 million for Fiscal Year 2001 (for a total of $100 million for Fiscal Year 2001), an additional $70 million for Fiscal Year 2002 (for a total of $100 million for Fiscal Year 2002), and $100 million for Fiscal Year 2003.

October 2002—NIH issued a detailed progress report, *Conquering Diabetes: Highlights of Program Efforts, Research Advances, and Opportunities,* on NIH-funded diabetes research. The report describes research achievements and initiatives since 1999, when the Diabetes Research Working Group published its 5-year plan. The Congressionally established Group made scientific recommendations in 5 areas of extraordinary research opportunity: the genetics of diabetes, autoimmunity and the beta cell, cell signaling and cell regulation, obesity, and clinical research and clinical trials. The Group also made recommendations regarding the microvascular and macrovascular complications of diabetes, the special populations most affected by diabetes, and resource and infrastructure needs to further diabetes research.

December 17, 2002—President Bush signed into law H.R. 5738, a bill that will increase and extend funding for the Special Diabetes Program (formerly P.L. 105-33). The bill provides $750 million for type 1 diabetes research over a period of 5 years (FY 04-FY 08).

December 2002—The Public Health Service Act Amendment for Diabetes (P.L. 107-360) extended and augmented the Special Statutory Funding Program for Type 1 Diabetes Research in time and amount, allocating $150 million per year for fiscal years 2004 through 2008.

December 8, 2003—The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173). Title VII, Subtitle D, Section 733 of this law, entitled "Payment for pancreatic islet cell investigational transplants for Medicare beneficiaries in clinical trials," specifies that the Secretary, acting through NIDDK, conduct a pancreatic islet transplantation clinical trial that includes Medicare beneficiaries, and that Medicare cover the routine costs, the transplantation, and appropriate related items and services for the Medicare beneficiaries enrolled in the trial.

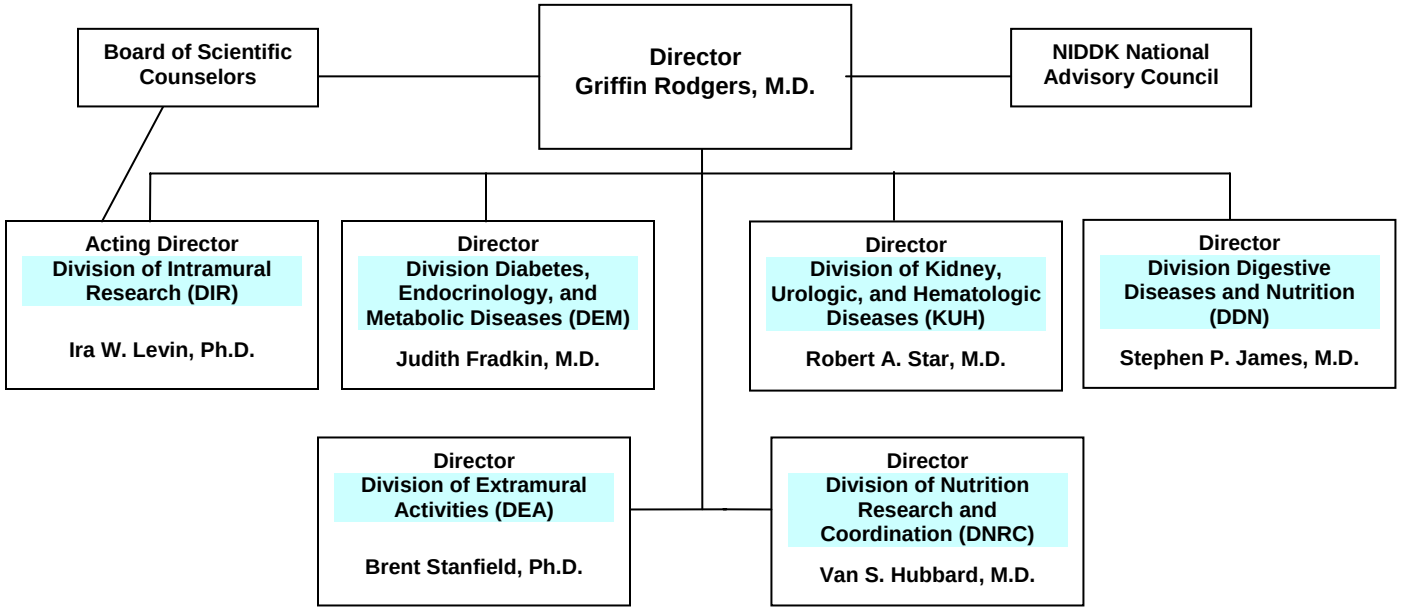
October 25, 2004—The Pancreatic Islet Cell Transplantation Act of 2004(P.L. 108-362) amended the Public Health Service Act for the purposes of increasing the supply of pancreatic islet cells for research, and providing for better coordination of Federal efforts and information on islet cell transplantation. A provision of this law specified that the annual reports prepared by the Diabetes Mellitus Interagency Coordinating Committee, which is led by the NIDDK, include an assessment of the Federal activities and programs related to pancreatic islet transplantation.

September 2004—The reports accompanying the FY 2005 Senate and House Labor, HHS, Education appropriations bills (reports 108-345 and 108-636, respectively) called on the NIH and HHS to establish a national commission on digestive diseases to review the burden of digestive diseases in the United States and develop a long-range research plan to address this burden. The NIH Director subsequently established the National Commission on Digestive Diseases, under NIDDK leadership, in August 2005. Commission activities included public meetings, review of a report by the Digestive Diseases Interagency Coordinating Committee on the burden of digestive diseases in the United States, and the development of a Long-Range Plan for Digestive Diseases Research.

NIDDK Directors

Name	In Office from	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999
Allen M. Spiegel	November 15, 1999	March 3, 2006
Griffin P. Rodgers	April 1, 2007	present

NIDDK Organizational Chart



Overview of the Office of the Director

In addition to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC), the Office of the Director includes the following offices:

- Executive Office, including administrative components:
  - — Ethics Office
  - — Office of Workforce Development and Planning (OWDP)
  - — Office of Management and Policy Analysis (OMPA)
  - — Office of Financial Management and Analysis (OFMA)
  - — Extramural Administrative Management Branch (EAMB)
  - — Intramural Administrative Management Branch (IAMB)
  - — Computer Technology Branch (CTB)
- Office of Communications and Public Liaison (OCPL)
- Office of Scientific Program and Policy Analysis (OSPPA)

Also within the Office of the Director are the following two research coordination offices.

The NIDDK director created the ***Office of Minority Health Research Coordination*** *(OMHRC)* to address the burden of diseases and disorders that disproportionately impact the health of minority populations. The OMHRC will help implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Center on Minority Health and Health Disparities at NIH.

The NIDDK ***Office of Obesity Research*** (OBR) is responsible for coordination of obesity-related research within NIDDK, and carries out its functions through the NIDDK Obesity Research Working Group. The Office is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch, the Office of Scientific Program and Policy Analysis (OSPPA), and the Division of Nutrition Research Coordination (DNRC). The responsibilities of the NIDDK Obesity Research Working Group are: (1) to provide a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities; (2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; (3) to identify and plan appropriate workshops and conferences; and (4) to assist in the preparation of obesity-related reports and inquiries.

Under the auspices of the NIDDK Advisory Council, the National Task Force on Prevention and Treatment of Obesity was established in June 1991. In June 2003, the name was changed to the *Clinical Obesity Research Panel (CORP)*. The mission of the CORP is to synthesize current scientifically based information on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature. It is composed of leading obesity researchers and clinicians who advise the institute on research needs and sponsor workshops on topics related to the prevention and treatment of obesity. The CORP serves in an advisory capacity to the Weight-control Information Network (WIN).

Biographical Sketch of NIDDK Director Griffin P. Rodgers, M.D., M.A.C.P.

Dr. Griffin P. Rodgers was named Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—one of the National Institutes of Health (NIH)—on April 1, 2007. He had served as NIDDK's Acting Director since March 2006 and had been the Institute's Deputy Director since January 2001. Dr. Rodgers also has been chief of the Molecular and Clinical Hematology Branch since 1998; the branch is now administratively managed by NIH's National Heart, Lung and Blood Institute.

Dr. Rodgers received his undergraduate, graduate, and medical degrees from Brown University in Providence, R.I. He performed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology/oncology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. In addition to his medical and research training, he earned a master's degree in business administration, with a focus on the business of medicine, from Johns Hopkins University in 2005.

As a research investigator, Dr. Rodgers is widely recognized for his contributions to the development of the first effective—and now FDA approved—therapy for sickle cell anemia. He was a principal investigator in clinical trials to develop therapy for patients with sickle cell disease. He also performed basic research that focused on understanding the molecular basis of how certain drugs induce gamma-globin gene expression. He was honored for his research with numerous awards including the 1998 Richard and Hinda Rosenthal Foundation Award, the 2000 Arthur S. Fleming Award, the Legacy of Leadership Award in 2002, and a Mastership from the American College of Physicians in 2005.

Dr. Rodgers has been an invited professor at medical schools and hospitals in France, Italy, China, Japan, and Korea. He has been honored with many named lectureships at American medical centers and has published over 150 original research articles, reviews, and book chapters and has edited 4 books and monographs.

Dr. Rodgers served as Governor to the American College of Physicians for the U.S. Department of Health and Human Services from 1994 to 1997. He is a member of the American Society of Hematology, the American Society of Clinical Investigation, and the Association of American Physicians, among others. He is the chair of the Hematology Subspecialty Board and is a member of the American Board of Internal Medicine Board of Directors. He is board certified in Internal Medicine, in Emergency Medicine, and in Hematology.

Website: http://www2.niddk.nih.gov/AboutNIDDK/Director/default.htm

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Overview of the Division of Intramural Research

The Intramural Research Program (IRP) of the NIDDK conducts basic, translational, and clinical biomedical research related to: diabetes mellitus, endocrine, bone and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; kidney diseases; and hematologic diseases. Intramural research is conducted in the Institute's laboratories and clinical facilities in Bethesda, Maryland, and in Phoenix, Arizona.

The research conducted in the IRP spans the breadth of modern biomedical investigation, from basic science to clinical studies. A sampling of areas under study includes:

- Biophysics – studies of protein folding, development of optical and vibrational imaging, and theory of protein dynamics;
- Cell biology – studies of nuclear import/export, intracellular protein and lipid trafficking, cellular migration and prions;
- Chemical biology and medicinal chemistry – synthesis and characterization of novel compounds and discovery of biologically active natural products;
- Developmental biology – studies using model systems ranging from slime molds to vertebrates to human cells;
- Genetics, pathogenesis and novel therapies of disease – studies of diabetes types 1 and 2, hepatitis, lipodystrophy, multiple endocrine neoplasia, nephritis/nephropathy, obesity, sickle cell anemia and transplantation;
- Molecular biology – studies of chromatin structure and function, transcriptional regulation and DNA recombination;
- Signal transduction – basic and human disease-oriented studies of GTP-binding proteins and GTP-binding protein-coupled receptors, tyrosine kinase receptors and nuclear hormone receptors; and
- Structural biology – studies using x-ray crystallography and NMR spectroscopy.

In addition to its 12 Branches and 10 Laboratories, the IRP includes a section on veterinary sciences, a section on biological chemistry, the Office of Technology Transfer, the Office of Fellow Recruitment and Career Development, and an Administrative Management Branch. Six core laboratories provide scientific support services to investigators.

Website: http://www2.niddk.nih.gov/NIDDKLabs/

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Overview of the Division of Extramural Activities

The Division of Extramural Activities (DEA) is responsible for coordinating the receipt, referral and scientific review of extramural research applications and proposals before funding, and for the processing of awards for grants, cooperative agreements and contracts. It logs in, assigns and internally distributes all extramural applications and proposals received by the NIDDK and conducts scientific and technical peer review for grant applications and contract proposals requiring special programmatic consideration.

DEA coordinates the Institute's Committee Management Activities and the meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council. Finally, the DEA performs and coordinates programmatic analysis and evaluation activities. Organizationally the Division has three primary functional components:

The ***Grants Management Branch*** is the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NIDDK.

The ***Scientific Review Branch*** coordinates the initial scientific peer review of applications submitted in response to Request for Applications (RFAs), training and career awards, program projects, multi-center clinical trials and research contracts, including Loan Repayment Program applications. Most R01s, R21s, Fellowship and SBIR grant applications are reviewed in the Center for Scientific Review.

The ***Office of Research Evaluation and Operations (OREO)*** oversees the Institute's categorical disease coding function and performs grant and expenditure reporting on disease/organ topics. The office also oversees the Institute's grant referral functions, provides technical support and coordination of the IMPAC II System, and assists with tracking and administration of the Loan Repayment Program (LRP). At the request of the Director or extramural divisions, the office conducts quantitative and qualitative data analyses, develops special reports, and contributes to responses to congressional, disease advocate and public inquiries. The office also plays a key roll in coordinating and supporting NIDDK Advisory Council activities.

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/DEA/

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Overview of the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM)

DEM supports research and research training related to diabetes mellitus, endocrinology, and metabolic diseases, including cystic fibrosis. In addition, the Division leads the administration of the Trans-NIH Diabetes Program and coordinates federally supported diabetes-related activities.

Diabetes Research Programs

The ***Adipocyte Biology Research Program*** encompasses research that addresses the development and physiology of the adipocyte cell. Specific areas of support include studies on the properties of transcription factors that regulate adipocyte differentiation; research on the consequences of insulin action on adipocyte physiology; and use of animal and tissue culture models to understand adipocyte biology.

The ***Autoimmunity/Viral Etiology of Type 1 Diabetes Research Program*** emphasizes support of investigator-initiated basic and clinical research relating to autoimmune endocrine diseases, including type 1 diabetes and autoimmune thyroid disease (AITD). Applications that address the etiology and pathogenesis of type 1 diabetes, immunology, and viral etiology of diabetes are included. Studies utilizing animal models to further our understanding of type 1 diabetes are of continuing interest to this program. Studies that emphasize autoimmune thyroid disease, including Graves' disease, Hashimoto's thyroiditis, and their complications, are included. Humanized animal models of AITD are also included.

The ***Behavioral/Prevention Research Program*** encompasses individual, family, and community-based strategies aimed at prevention of diabetes and its complications through lifestyle modifications, education, and other behavioral interventions. Particular emphasis is placed on development of culturally sensitive, lifestyle interventions to prevent or treat diabetes in diverse high-risk populations including African Americans, Hispanic Americans, and Native Americans. Specific areas of research include the link between behavior and physical health as it relates to diabetes and complications; approaches to improving health-related behaviors and to enhancing diabetes self-management; and other aspects of diabetes care.

The ***Beta Cell Therapy Research Program*** focuses on research to develop alternative cell or tissue sources, as well as an understanding of the basic mechanisms that support regeneration or neogenesis of pancreatic islets. This program supports research in the following areas:

- Developing methods to expand pancreatic islets or beta cells for transplantation
- Optimizing growth conditions for islet cell proliferation and differentiation
- Deriving pancreatic islets from stem/precursor cells
- Assessing alternative cell or tissue sources by transplantation
- Animal models of islet regeneration and neogenesis.

The ***Clinical Islet Transplantation Consortium*** develops and implements a program of single- and/or multi-center clinical studies, accompanied by mechanistic studies, in islet transplantation with or without accompanying kidney transplantation, for the treatment of type 1 diabetes.

The ***Clinical Research in Type 2 Diabetes Program*** will focus on patient-oriented research (i.e., clinical studies and small clinical trials) related to:

- Pharmacologic interventions and/or lifestyle interventions to prevent or treat type 2 diabetes, including studies relevant to new drug development
- Development of surrogate markers for use in clinical trials for the prevention or treatment of type 2 diabetes
- Cellular therapies for the treatment of type 2 diabetes
- Improving the care of patients with type 2 diabetes

The *Complications of Diabetes Research Program* encompasses basic and clinical research related to acute (e.g., ketoacidosis and hyperosmolar coma) and chronic complications of type 1 and type 2 diabetes. Chronic complications include the vascular complications of diabetes and the effects of diabetes on any organ system. Clinical studies supported under this program include strategies to prevent or treat the complications of diabetes. Supported basic research examines the molecular and cellular mechanisms by which hyperglycemia mediates its adverse effects and the interrelationships among the mechanisms potentially involved in the pathogenesis of complications, including increased polyol pathway flux, alterations of intracellular redox state, oxidative stress, glycation of structural and functional proteins, altered expression of growth factors, enhanced activity of PKC, impaired synthesis of nitric oxide and other vasoactive substances, and altered metabolism of fatty acids.

The ***Developmental Biology Research Program*** supports research related to developmental genetic screens for identifying mutations that affect the formation of tissue such as bone, adipose, endocrine pancreas, or pituitary. Specific areas of support also include signals, signaling pathway components, and transcriptional factors that regulate pattern formation in the embryo, or control the fate, specifications, proliferation, and differentiation of cells in the formation of tissues and organs.

The ***Diabetes Centers Program*** administers 2 types of center awards, the Diabetes Endocrinology Research Centers (DERC) and the Diabetes Research and Training Centers (DRTC). An existing base of high-quality diabetes-related research is a primary requirement for establishment of either type of center. While not directly funding major research projects, both types of center grants provide core resources to integrate, coordinate, and foster the interdisciplinary cooperation of a group of established investigators conducting research in diabetes and related areas of endocrinology and metabolism. The 2 types of centers differ in that the DERC focuses entirely on biomedical research, while the DRTC has an added component in training and translation.

The ***Diabetes Mellitus Interagency Coordinating Committee (DMICC)***, established in 1974 and chaired by the DEMD Director, includes representatives from all Federal departments and agencies whose programs involve health functions and responsibilities relevant to diabetes mellitus and its complications. Functions of the DMICC include coordinating the research activities of NIH and those activities of other Federal programs that are related to diabetes mellitus and its complications; ensuring the adequacy and soundness of these activities; and providing a forum for communication and exchange of information necessary to maintain coordination of these activities.

The ***Drug Discovery Program*** supports:

- Interdisciplinary activities and resources that increase understanding of physiological and pathophysiological processes relevant to therapeutic development in diabetes, endocrine, and metabolic disorders
- Research that seeks to elucidate molecular structures or biological pathways that may lead to the identification and validation of targets that can be potentially manipulated by ligands/inhibitors. "Druggable" molecular targets/pathways

- Studies of the potential bioavailability of compounds, the ability to modulate selectively the function of drug discovery targets, and the ability to translate biological endpoints of preclinical research to the clinic showing high potential for success in later stage drug development
- Development of high-throughput assays based on biologic pathways likely involved in the pathogenesis of diabetes and its complications that could be used to screen molecular libraries for novel therapeutic agents
- Research that seeks to discover new mechanisms of action for therapeutics used for diabetes, endocrine, and metabolic disorders, and the development and validation of disease models to evaluate novel therapeutics for these disorders.

The ***Endocrine Pancreas Research Program*** includes projects to elucidate the basic biology of the endocrine cells of the pancreas, which include alpha, beta, and delta cells within the islet. These include insulin or other hormone synthesis and secretion,;coupling of nutrient sensing to insulin secretion; cell interactions; role of incretins, cytokines, other hormones, and enervation; studies of apoptosis and cell turnover in the adult organ; metabolism, basic signal transduction, and regulation of gene transcription, especially as these areas relate to beta cell and islet function. This program also contains studies in cell culture to bioengineer glucose-responsive hormone-secreting cells or islets for eventual treatment of diabetes.

The ***Environmental Determinants of Diabetes in the Young (TEDDY) Program*** is a multi-center, multi-national, epidemiological study to identify infectious agents, dietary factors, or other environmental exposures that are associated with increased risk of autoimmunity and type 1 diabetes.

The *Genetics of Type 1 Diabetes Research Program* seeks to identify the genes that predispose to the development of type 1 diabetes and studies to determine their mechanism. Specific areas of support include:

- Studies of animal models of type 1 diabetes such as the NOD mouse and the BB rat to identify genes responsible for the development of type 1 diabetes
- Studies of the HLA region that contains the major genetic determinant for type 1 diabetes to understand its contribution to the development of diabetes
- Studies of immune regulatory regions that may contribute to both type 1 diabetes as well as other autoimmune disorders
- Development of genetic resources and patient samples for studies of type 1 diabetes
    - Creation of animal models for therapeutic trials

The ***Genetics of Type 2 Diabetes Research Program*** seeks to identify genes that contribute to the development of type 2 diabetes mellitus. Specific areas of support include using animal models to identify diabetes genes; studies using quantitative statistical methods to identify diabetes genes in human populations; and development of genetic resources, patient samples, and methods for studying genetic linkage for diabetes.

The ***Glucose Sensors Research Program*** will contain projects aimed at developing or implementing glucose sensors that can determine glucose concentration in the plasma, interstitial fluid, or other appropriate space in diabetic patients continuously or in repeated samples. This program also includes development of the necessary components of glucose sensors (such as biocompatible materials or fluorescent glucose ligands, new sampling systems, etc.), software, mathematical algorithms and circuitry designed for calibration or insulin pump control, and devices that combine these sensors with insulin delivery systems in a ”closed-loop” artificial pancreas.

The ***Hypoglycemia in Diabetes Research Program*** encompasses clinical and basic studies on the pathogenesis, prevention, treatment, and sequelae (including hypoglycemia unawareness) of hypoglycemia in both type 1 and type 2 diabetes. Specific areas of research include studies to identify the neuronal and hormonal systems involved in recognition and response to hypoglycemia; examine the interplay of counterregulatory endocrine responses; and ascertain the regulatory mechanisms for glucose homeostasis and the cells involved in this regulation.

The ***Insulin Receptor/Structure/Function/Action Research Program*** encompasses studies of the structure, function, and action of the insulin receptor. Specific areas of support include:

- Molecular analysis of ligand binding to receptor
- Activation of the tyrosine kinase
- Subsequent insulin receptor function in signal transduction by serving as a platform for the attachment of downstream signaling molecules involved in insulin action
- Insulin Receptor Signaling proteins (IRS)-1,2,3,4, and other proteins containing Src Homology Domains (e.g., SH2)

The ***Islet Transplantation Research Program*** encompasses studies of therapeutic or preclinical approaches to treat diabetes. Specific areas include: Transplantation of pancreas, pancreatic endocrine cells (islets or beta cells), beta cells in culture or other insulin-producing cells in humans or animal models (including procedures to enhance tolerance, encapsulate/immunoisolate islets or other means to improve transplant survival). The program also includes gene therapy or other approaches to manipulate islets to improve viability, durability, or other aspects of transplantation.

The ***Molecular and Functional Imaging Program*** comprises projects that employ novel molecular and functional imaging techniques to visualize various aspects of diabetes and obesity, endocrinology, metabolism, and metabolic diseases. The emphasis will be on in vivo techniques (PET, MRI, Ultrasound, CT, optical tomography, etc.), with applications serving to tag tissues and cells of interest; study biological processes in vivo; diagnose disease; or monitor progress during therapy. These will be studies either to monitor physiological or metabolic processes, rate of metabolism, blood flow, sites of hormone action, etc., using imaging and spectroscopic techniques or to identify cell types using molecular imaging probes. Another application might be the technology to develop a probe to identify in vivo the sites within the hypothalamus that control satiety.

The ***Mouse Metabolic Phenotyping Program*** contains a consortium of centers with the purpose of phenotyping mouse models of diabetes and its complications, obesity, or other chronic metabolic diseases. It will include the development of new tests for phenotyping mice, adaptation or miniaturization of existing tests, as well as the performance of these tests to more fully characterize new or existing models of disease. Emphasis is placed on noninvasive or minimally invasive technologies that can be used for longitudinal studies, but this program also includes high-throughput metabolic screens. Examples include glucose and insulin clamps; miniaturized assays for hormones, cytokines, nutrients, or intermediary metabolites; kinetic measures of metabolic processes; immunological parameter; measurements of energy balance, body composition, and activity; measures for metabolic, behavioral, and physiologic abnormalities during disease progression.

The ***National Diabetes Data Group (NDDG)*** serves as the major Federal focus for the collection, analysis, and dissemination of data on diabetes and its complications. Drawing on the expertise of the research, medical, and lay communities, the NDDG initiates efforts to:

- Define the data needed to address the scientific and public health issues in diabetes
- Foster and coordinate the collection of these data from multiple sources

- Identify important data sources on diabetes, and analyze and promulgate the results of these analyses to the scientific and lay public
- Promote the timely availability of reliable data to scientific, medical, and public organizations and individuals
- Modify data reporting systems to identify and categorize more appropriately the medical and socioeconomic impact of diabetes
- Promote the standardization of data collection and terminology in clinical and epidemiologic research
- Stimulate development of new investigator-initiated research programs in diabetes epidemiology.

The ***National Diabetes Education Program (NDEP)***, co-sponsored by the NIDDK and the CDC, is focused on improving the treatment and outcomes for people with diabetes, promoting early diagnosis, and ultimately preventing the onset of diabetes. The goal of the program is to reduce the morbidity and mortality associated with diabetes through public awareness and education activities targeted to the general public, especially those with at risk for type 2 diabetes, people with diabetes and their families, health care providers, and policy makers and payers. These activities are designed to:

- Increase public awareness that diabetes is a serious, common, costly, and controllable disease that has recognizable symptoms and risk factors
- Encourage people with diabetes, their families, and their social support systems to take diabetes seriously and to improve practice of self-management behaviors
- Reduce disparities in health care in racial and ethnic populations disproportionately affected by diabetes
- Alert health care providers to the seriousness of diabetes, effective strategies for its control, and the importance of a team care approach to helping patients manage the disease. Toward these ends, the NDEP is developing partnerships with organizations concerned about diabetes and the health care of its constituents.

The ***Prevention of Type 1 Diabetes Research Program*** includes studies on drug development and cellular therapy that are being proposed to prevent type 1 diabetes. Areas of particular interest are:

- Studies on drug development for type 1 diabetes treatment or prevention
- Studies including the creation of animal models for therapy trials or humans to maintain normal blood glucose levels
- Tolerance induction for prevention of type 1 diabetes
- Immune intervention
- "Humanized" mouse model (development of transgenic NOD with human HLA molecules on the T cells) for type 1 diabetes
- Development of therapies for prevention of Impaired Glucose Tolerance (IGT) or interventions to prevent conversion of IGT to type 1 diabetes
- Drugs designed to enhance peripheral glucose metabolism or reduce hepatic glucose production of type 1 diabetics
- Therapies designed to increase insulin sensitivity of type 1 diabetics.

The ***Type 1 Diabetes Clinical Trials Program*** supports large, multi-center clinical trials conducted under cooperative agreements or contracts. One primary prevention trial has concluded. The Diabetes Prevention Trial Type 1 (DPT-1) was aimed at determining whether it was possible to prevent or delay the onset of type 1 diabetes in individuals determined to be at immunologic, genetic, and/or metabolic risk. It also supported future clinical trials of the Type 1 Diabetes TrialNet, which will conduct intervention studies to prevent or slow the progress of type 1 diabetes, and natural history and

genetics studies in populations screened for or enrolled in these studies. The program also supports the Epidemiology of Diabetes Interventions and Complications (EDIC) study, an epidemiologic follow-up study of the subjects previously enrolled in the Diabetes Control and Complications Trial (DCCT).

The ***Type 2 Diabetes Clinical Trials Program*** supports large, multi-center clinical trials conducted under cooperative agreements or contracts. One primary prevention trial is underway. The Diabetes Prevention Program (DPP) is focused on testing lifestyle and pharmacological intervention strategies in individuals at genetic and metabolic risk for developing type 2 diabetes to prevent or delay the onset of this disease.

The ***Type 2 Diabetes in the Pediatric Population Research Program*** encompasses research on the pathophysiology, prevention, and treatment of type 2 diabetes in children. Specific areas of support include studies:

- To describe the epidemiology (incidence, prevalence, risk factors) of type 2 diabetes and its complications in children
- To develop diagnostic criteria to distinguish type 1 and type 2 diabetes in children
- To define the metabolic abnormalities (and the natural history of such abnormalities) in children with type 2 diabetes
- To develop practical, effective strategies for the prevention and/or treatment of type 2 diabetes in children
- To understand the basis for race/ethnic disparities in the incidence of type 2 diabetes in the pediatric population.

Endocrinology Research Programs

The ***Bone and Mineral Metabolism Research Program*** encompasses basic and clinical research on the hormonal regulation of bone and mineral metabolism in health and disease. Specific areas of support include:

- Endocrine aspects of disorders affecting bone, including osteoporosis, Paget's disease, renal osteodystrophy, and hypercalcemia of malignancy
- Pathogenesis, diagnosis, and therapy of parathyroid disorders, including primary or secondary hyperparathyroidism;
- Effects of parathyroid hormone, parathyroid hormone-related protein, calcitonin, vitamin D, estrogen, retinoic acid, growth factors (e.g., IGF-I), glucocorticoids, thyroid hormone, and other systemic or local-acting hormones and their receptors on bone metabolism
- Bone active cytokines (e.g., TGF-b, BMPs, CSF-1)
- Studies of calcium homeostasis, absorption, metabolism, and excretion, including the calcium-activated receptor
- Basic and clinical studies of vitamin D
- Bone morphogenesis, including the roles of developmental factors in bone formation (e.g., hedgehogs, Hox genes)

The ***G-Protein Coupled Receptors Program*** encompasses studies on the G-protein coupled receptor superfamily. Specific areas of support include:

- Cell surface, or 7-transmembrane domain, receptors coupled to GTP-binding ("G")- proteins for signal transduction (e.g., beta-adrenergic receptor)
- Receptor structure

- Receptor down-regulation (homologous desensitization)
- Role(s) of mutated receptors in disease
- Coupling of signaling through the receptor to other membrane-bound effectors and or regulators, such as adenylyl cyclase, ion channels, protein phosphatases or kinases, and other receptors.

Signal transduction through GPCRs also includes mechanisms of regulation of gene expression through nuclear proteins such as the Cyclic Nucleotide Response Element Binding Protein (CREB) and the CREB-binding protein.

The ***Integrative Biology of Obesity Program*** supports both basic and clinical research investigating the neural and endocrine mechanisms contributing to obesity and the pathophysiological consequences of obesity, particularly type 2 diabetes. Also included are studies that explore the neuronal and peptidergic pathways regulating food intake and other behaviors influencing body adiposity. Thus, proposals encompassed by this program will take an integrative approach to the goal of elucidating the physiological and behavioral factors contributing to the etiology of obesity. Clinical studies that expand on basic research findings and/or explore basic mechanisms involved in human obesity are encouraged. Examples of areas of interest include: Neurobiology of human obesity and behavior, neuropeptides and their receptors involved in the regulatory pathways controlling feeding behavior, satiety and energy expenditure, intrauterine and neonatal environment in the development of obesity, and imaging of neural pathways involved in the regulation of food intake.

The ***Intracellular Signal Transduction Research Program*** encompasses research aimed at understanding the structure and function of intracellular signal-transducing molecules. Specific areas of support include:

- Intracellular kinases, phosphatases, and anchoring proteins
- Signaling mechanisms that have altered activity in response to protein phosphorylation, calcium, and cAMP
- Approaches to solving the 3-dimensional structure of signaling proteins including crystallography and NMR
- Functional analysis of these proteins, including comparison of wild-type and naturally occurring or synthetic, mutant proteins, or expression of dominant-negative forms of the proteins
- Microscopic techniques to localize these proteins within cells
- Identification of substrates for these signaling proteins
- Analysis of crosstalk among distinct signal transduction pathways

The ***Neuroendocrinology Research Program*** encompasses research on neuropeptides of the hypothalamus. Specific areas of research support include:

- Physiological response to stress through the hypothalamic-pituitary-adrenal axis
- Neuropeptides and neuropeptide receptor signaling pathways
- Gene regulation in the hypothalamus and pituitary gland
- Diseases of the pituitary including neoplasia
- Hypopituitary dwarfism
- Identification and characterization of novel hypothalamic or pituitary hormones
- Tissue-specific and developmental expression of pituitary and hypothalamic genes
- Pituitary hormone receptors and actions on target tissues (e.g., GH IGF-1 axis)
- Neuropeptide receptors in diagnosis and treatment of disease
- Neuroendocrine-immune interactions

The ***Nuclear Receptor Superfamily Program*** encompasses basic and clinical research on members of the steroid hormone superfamily (also known as the nuclear receptor superfamily). The program includes structure/function studies and the role in signal transduction and regulation of gene expression of:

- Steroid hormones, including glucocorticoids, mineralocorticoids, progesterone, estrogens, androgens (testosterone), and DHEA
- Nuclear receptors, including thyroid hormone, vitamin D, retinoids (RAR, RXR, vitamin A), PPARs, and orphan receptors (LXR, Nur77, COUP-TF, and others).

Topics covered include receptor structure, interaction with cytoplasmic chaperones (e.g., Hsp90, Hsp70, etc.), interaction with ligand, nuclear translocation, binding to hormone response elements, interaction with nuclear accessory proteins (e.g., SRC-1, N-CoR, CBP, histone acetylase/deacetylase, GRIP1, etc.), and regulation of gene expression.

The ***Regulation of Energy Balance and Body Composition Research Program*** encompasses research on regulation of body composition by the hypothalamus and circulating factors. Specific areas of support include:

- Endocrinology of body composition, including interactions between nutrition, exercise, and anabolic hormones
- Neuropeptides and their receptors involved in regulatory pathways controlling feeding behavior, satiety, and energy expenditure
- Interactions between hypothalamicpituitary adrenal axis and peripheral metabolic signals (e.g., insulin), leptin, and glucocorticoids
- Hormones and cytokines involved in wasting syndromes (e.g., cancer, AIDS)
- Endocrine regulation of energy balance via uncoupling proteins
- Hypothalamic integration of peripheral endocrine and metabolic signals

Metabolic Diseases Research Programs

The ***Functional Metabolomics Program*** includes grants focused on the application of technology used to measure large-scale integrated metabolism of cells, tissues, and organ system. These studies can be done in vivo, in isolated tissue, or in cell culture. They have a focus on applying novel technology advancements in measuring and identifying many metabolites within multiple pathways. Emphasis is on discovering new, potentially mechanistic relationships between changes in metabolite profile and the etiology or pathology of specific metabolic diseases or syndromes that fall within NIDDK's scope of research. Important goals include in vivo and translational potential of technology to rapidly analyze and interpret large networks of pathways and fluxes to gain a more complete view of metabolome dynamics.

The ***Gene Therapy and Cystic Fibrosis Centers Program*** supports 3 types of centers: Gene Therapy Centers (P30), Cystic Fibrosis Research Centers (P30), and Specialized Centers for Cystic Fibrosis Research (P50). Gene Therapy Centers provide shared resources to a group of investigators to facilitate development of gene therapy techniques and to foster multidisciplinary collaboration in the development of clinical trials for the treatment of cystic fibrosis and other genetic metabolic diseases. Cystic Fibrosis Research Centers and Specialized Centers for Cystic Fibrosis Research provide resources and support research on many aspects of the pathogenesis and treatment of cystic fibrosis.

The ***Cystic Fibrosis Research Program*** supports investigator-initiated research grants encompassing both fundamental and clinical studies of the etiology, molecular pathogenesis, pathophysiology,

diagnosis, and treatment of cystic fibrosis and its complications. Particular areas of emphasis of the program include:

- Characterization of the cystic fibrosis gene, its mutations, and the molecular mechanisms by which mutations cause dysfunction
- Studies of the cystic fibrosis transmembrane regulator (CFTR) protein encoded by the cystic fibrosis gene, including its processing, trafficking, and folding, and the mechanisms by which mutations alter CFTR trafficking and structure/function
- Elucidation of the pathways of electrolyte transport in affected epithelia and the relationship between CFTR and other epithelial ion channels
- Elucidation of the potential roles of CFTR in the transport of molecules other than chloride, posttranslational processing of mucins and other proteins, exocytosis and recycling of cell membranes, subcellular organelle function, and other cellular processes
- Studies of the relationship between genotype and phenotype in cystic fibrosis and identification of genetic or environmental factors that explain the variable clinical presentations and severity of disease
- Delineation of the mechanisms underlying the inflammation and infection characteristic of cystic fibrosis. Analysis of how mutations in the cystic fibrosis gene and alterations in CFTR function result in inflammation and infection
- Research on other clinical manifestations of cystic fibrosis, including the pathophysiologic mechanisms underlying malnutrition and growth failure, impaired fertility, liver disease, and overall physical and psychosocial development. Investigation of approaches to ameliorate the complications of cystic fibrosis
- Development of potential therapeutic approaches to modulating the transport defect in cystic fibrosis and to stabilize mutant CFTR and enhance its targeting and integration into the cell membrane
- Development of safe and effective methods for gene therapy
- Development of animal or cell models useful for studying cystic fibrosis and its therapy
- Evaluation of therapeutic interventions in cystic fibrosis in clinical studies or animal models

The ***Gene Therapy Research Program*** encompasses research aimed at developing basic and applied gene therapy for genetic metabolic diseases. Specific areas of support include:

- Pilot and feasibility studies (R21) to improve gene delivery systems
- Studies of the basic science of AAV, adenovirus, retrovirus, and lentivirus vectors
- Studies of non-viral methods of gene transfer such as liposomes or DNA-conjugates
- Studies to target gene delivery to specific cell types
- Gene therapy of stem cells to treat a genetic metabolic disease

The ***Genomic Resource and Technology Development Program*** supports projects that take advantage of recent development in genetic analysis, genomic-based technologies, and systems biology to propose innovative ways of understanding the biological networks behind diseases of interest to NIDDK, such as metabolic disease. Emphasis will be put on assembling a community of researchers to propose integrated approaches and develop new tools to solve complex problems that are difficult to tackle in a traditional laboratory setting and that require multi-disciplinary teams. Areas of interest include:

- Genome-wide analysis of transcriptional regulatory networks in health and disease
- Tissue development and regeneration
- Functional genomics in disease-relevant organs under normal and pathological conditions

- Forward and reverse chemical genetics to explore regulatory networks involved in disease biology
- Development of high-throughput, cell-based screening platforms to interrogate basic and disease biology
- Development of partnerships and integrated research projects between physicians, geneticists, computational scientists, biochemists, and others, to better identify the underlying causes of complex diseases

The ***Inborn*** *Errors of Metabolism Research Program* encompasses research in the pathophysiology and treatment of genetic metabolic diseases. Specific areas of support include:

- Studies of etiology, pathogenesis, prevention, diagnosis, pathophysiology, and treatment of these diseases
- Characterization of the genes, gene defects, and regulatory alterations that are the underlying causes of these diseases
- Studies of the mutant enzyme and its effect on the structure and function of the protein
- Development of animal models for genetic disease
- Development and testing of dietary, pharmacologic, and enzyme replacement therapies
- Development of stem cell transplantation both prenatally and postnatally as a treatment for metabolic diseases

The ***Integrative Metabolism and Insulin Resistance Program*** comprises grants that study intermediary metabolism and physiology on the whole-body, organ, and cell level. These studies can be done in vivo, in isolated tissues, or in cell culture. They focus on flux and regulation of either a single metabolic pathway, interacting pathways in a cell or organ, or interactions between organs in the whole body. Especially important are in vivo measurements of whole-body flux, such as glucose production or turnover, or blood flow. Examples of important goals for these studies include an understanding of insulin resistance, regulation of gluconeogenesis and glucose disposal, protein turnover rate and regulation, cellular and whole-body lipid fluxes, interaction between carbohydrate and lipid metabolism, rate of tricarboxylic acid cycle flux and energy production in the cell, transcriptional regulation of important flux regulating enzymes or transporters for a given pathway, etc.

The ***Metabolomics Technology Development Roadmap Program*** promotes development of novel technologies to study cellular metabolites, such as lipids, carbohydrates, and amino acids. Knowledge gained from these studies will be used to understand more precisely the role of metabolites in the context of cellular pathways and networks.

The ***Protein Trafficking/Secretion/Processing Research Program*** encompasses research aimed at understanding the mechanisms that account for the fate of proteins after their initial translation. Specific areas of support include:

- Protein folding
- Post-translational modifications and the enzymes that catalyze them
- Movement of proteins in vesicles from the endoplasmic reticulum through the Golgi and endosomes and their ultimate secretion
- Mechanisms that account for vesicle formation (pinching off) and vesicle fusion, which are paramount to understanding trafficking
- Movement of proteins in the direction opposite of secretion, including endocytosis and retrograde transport
- Proteins and small molecules that regulate protein trafficking

- Proteasomes, ubiquitin conjugation, and the N-end rule

The ***Proteomics in Diabetes, Endocrinology, and Metabolic Diseases Program*** comprises grants that study the structure, mechanism, kinetics, and regulation of isolated purified proteins. This would include x-ray crystallography, mass spectroscopy, electron microscopy, nuclear magnetic resonance, and mutational studies of structure. It also includes studies of subunit interactions and interactions with small regulatory ligands, substrates, intermediates, and products. Of special interest are new technologies for structure determination (especially membrane proteins), crystallization, identification of interacting molecules and proteins, and assignment of function to unknown gene products of interest to the fields of diabetes, endocrinology, and metabolic diseases. High-throughput methods are highlighted. All informatics associated with the field of proteomics are included.

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/DEM/

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Overview of the Division of Digestive Diseases and Nutrition

This Division supports research related to liver and biliary diseases; pancreatic diseases; gastrointestinal diseases, including neuroendocrinology, motility, immunology, and digestion in the GI tract; nutrient metabolism; obesity; eating disorders; and energy regulation. The Division provides leadership in coordinating activities related to digestive diseases and nutrition throughout the NIH and with various other Federal agencies.

Gastrointestinal Disease Programs

Investigators supported by the ***Gastrointestinal Motility Program*** focus their research on the structure of gastrointestinal muscles, the biochemistry of contractile processes and mechanochemical energy conversion relations between metabolism and contractility in smooth muscle, the extrinsic control of digestive tract motility, and the fluid mechanics of gastrointestinal flow. Other studies and areas of interest include the actions of drugs on gastrointestinal motility; intestinal obstruction; and diseases such as irritable bowel syndrome (functional digestive disorders), colonic diverticular disease, swallowing disorders, and gastroesophageal reflux.

The research emphasis of the ***Gastrointestinal Mucosa and Immunology Program*** focuses on intestinal immunity and inflammation. Areas of interest include ontogeny and differentiation of gut-associated lymphoid tissue; migratory pathways of intestinal lymphoid cells; humoral antibody responses; cell-mediated cytotoxic reactions and the role of cytotoxic effector cells in chronic intestinal inflammation; genetic control of the immune response at the mucosal surface; immune response to enteric antigens in both intestinal and extra-intestinal sites; granulomatous inflammation; lymphokines and cellular immune regulation; leukotriene/prostaglandin effects on intestinal immune responses; T-cell mediated intestinal cell injury; the intestinal mast cell and its role in intestinal inflammation; approaches to optimal mucosal immunoprophylaxis, including viral, bacterial, and parasitic diseases; diseases such as gluten-sensitive enteropathy, inflammatory bowel disease, and gastritis; malabsorption syndromes; diarrhea; gastric and duodenal ulcers; disease of the salivary glands (excluding cystic fibrosis); the effects of prostaglandins and other treatment modalities on the gastrointestinal tract; and the possible role of prostaglandins or other agents in the pathogenesis and treatment of digestive diseases.

The *Gastrointestinal Neuroendocrinology Research Program* supports basic and clinical studies on normal and abnormal function of both the enteric nervous system and the elements within the central nervous system that control the enteric nervous system. Neuroendocrine studies include histochemical and neurochemical analyses of the enteric nervous system, electrical properties of enteric ganglia, chemical neurotransmission, neural control of effector function, and extrinsic nervous input. This program places emphasis on gastrointestinal hormones and peptides, including their structure, biological actions, structure-activity relationships, receptors, distribution, quantitation, metabolism, release, correlation with physiological events, deficiency, and the role of time variation in the data collected in the above studies. In addition, the program supports studies on disease conditions associated with excessive or inadequate secretion of neuropeptides.

The ***Gastrointestinal Transport and Absorption Program*** supports research on the process of food digestion, and absorption and transport in the gastrointestinal tract, including the synthesis and assembly of digestive enzymes; the transport of water, ions, sugars, amino acids, peptides, lipids, vitamins, and macromolecules; and the formation, structure, and function of chylomicrons. Other areas of research focus on the regulation of gene expression in the gastrointestinal tract; the structure and function of the gut mucosa; the cytoskeletal structure and contractility in brush borders; the growth and differentiation of gastrointestinal cells in normal and disease states; intestinal

transplantation, storage, and preservation; and gastrointestinal tissue injury, repair, and regeneration. Also supported are studies on gastrointestinal diseases such as maldigestion and malabsorption syndromes.

The ***Acquired Immunodeficiency Syndrome Program*** encourages research into the characterization of intestinal injury, mechanism of maldigestion, and intestinal mucosal functions, as well as hepatic and biliary dysfunction in AIDS. In addition, studies are supported on mechanisms of nutrient dysfunction, deficiencies of various micronutrients nutritional management of the wasting syndrome and other aspects of malnutrition related to AIDS.

The ***Clinical Trials in Digestive Diseases Program*** supports patient-oriented clinical research focusing on digestive diseases. Small clinical studies (pilot), planning grants or phase III clinical trials may be appropriate to this program. The small clinical studies should focus on research that is innovative and/or potentially of high impact. They should lead to full scale clinical trials. Please see the current program announcement for small grants for clinical trials. Phase III clinical trials usually are multi-center and involve several hundred human subjects that are randomized to 2 or more treatments, 1 of which is usually a placebo. The aim of the trial is to provide evidence for support of, or a change in, health policy or standard of care. The interventions/treatments may include pharmacologic, nonpharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Areas of emphasis include: *Helicobacter pylori*; inflammatory bowel disease; functional bowel syndrome and constipation; non-ulcer dyspepsia; celiac disease; intestinal failure, short-gut syndrome, and small bowel transplantation.

The ***Digestive Diseases Research Core Centers Program*** provides a mechanism for funding shared resources (core facilities) that serve to integrate, coordinate, and foster interdisciplinary cooperation between groups of established investigators who conduct programs of high quality research that are related to a common theme in digestive disease research. An existing base of high-quality digestive disease-related research is a prerequisite for the establishment of a center. The research emphases of centers in this program presently focus on liver diseases, gastrointestinal motility, absorption and secretion processes, inflammatory bowel disease, structure/function relationships in the gastrointestinal tract, neuropeptides and gut hormones, and gastrointestinal membrane receptors. Due to a restriction on the number of core center grants that can be supported, new center grant proposals will be accepted only in response to a Request for Applications (RFA) announced in the *NIH Guide for Grants and Contracts.*

The ***Pancreas Program*** encourages research into the structure, function, and diseases (excluding cancer and cystic fibrosis) of the exocrine pancreas. Research efforts focus on:

- Neurohormonal factors involved in the regulation of pancreatic exocrine function in response to pathophysiological stimuli
- Studies on receptor and function of intra-cellular signal transducing molecules, coupling to downstream effectors
- Compartmentalization of enzymes, substrates, and their effectors
- Understanding post-translational mechanisms that account for the fate of proteins, including folding, trafficking, and secretion
- Understanding the properties and functions of intracellular and extracellular filamentous suprastructures that are involved in hormone signaling and exocrine pancreatic function.
- Studies on the biochemistry, etiology, pathogenesis, genetics, epidemiology, diagnosis, treatment, and prevention of disorders of the exocrine pancreas
- Development of experimental models

- Studies relating to development of the exocrine pancreas, including the growth and differentiation factors involved in this process and the characterization, isolation, production, and uses of pancreatic stem cells
- Studies on organ collection, preservation, and transplantation.

The ***Genetics and Genomics of Digestive Diseases Program*** supports research on identification of genes influencing predisposition to diseases of the gut, liver, and exocrine pancreas, as well as studies of control of gene expression during normal development and disease states of these organs.

Epidemiology Research

The ***Epidemiology and Data Systems Program*** serves as a focus for the collection, analysis, and dissemination of data on digestive diseases and their complications. The program:

- Identifies the data needed to address the scientific and public health issues in digestive diseases and nutrition
- Addresses the epidemiology of digestive diseases and nutritional disorders of public health significance, with particular emphasis on national surveys and their follow-up
- Promotes the timely availability of reliable data to pertinent scientific, medical, and public organizations
- Promotes the standardization of data collection and terminology in clinical and epidemiological research
- Works closely with members of the scientific community to develop investigator-initiated research in digestive diseases and nutrition epidemiology.

The program encourages research that addresses risk factors for disease occurrence and disease prognosis or natural history. The program also supports databases and biological repositories that support clinical and epidemiological studies in digestive diseases and nutrition.

Liver Disease Research Programs

The ***Liver and Biliary Program*** supports basic and clinical research on both the normal function and the diseases of the liver and biliary tract. Areas of basic research include:

- Hepatic regeneration; gene therapy; and liver cell injury, fibrosis, and apoptosis
- Basic and applied studies on liver transplantation, including techniques of preservation and storage
- Metabolism of bile acids and bilirubin
- Physiology of bile formation
- Control of cholesterol levels in bile
- Gallbladder and bile duct function.

Areas of disease-oriented research include:

- Cholesterol and pigment gallstones
- Inborn errors in bile acid metabolism
- Chronic hepatitis that evolves from autoimmune, viral, or alcoholic liver disease
- Various liver ailments such as Wilson's disease, primary biliary cirrhosis, primary sclerosing cholangitis, portal hypertension, hepatic encephalopathy, and Crigler-Najjar syndrome.

The ***Clinical Trials in Liver Disease Program*** supports patient-oriented clinical research in liver diseases to evaluate one or more experimental intervention(s) in comparison with a standard treatment and/or placebo control among comparable groups of patients. Experimental interventions may include pharmacologic, nonpharmacologic, and behavioral interventions given for disease prevention,

prophylaxis, diagnosis, or therapy. Areas of program emphasis in liver disease include non-alcoholic steatohepatitis (NASH); chronic hepatitis C; primary biliary cirrhosis; primary sclerosing cholangitis; prevention, management, and treatment of portal hypertension; and recurrent liver disease after transplantation. Either pilot studies or phase III trials may be appropriate. A phase III clinical trial usually involves several hundred or more comparable human subjects, the aim of the trial being to provide evidence for support of, or a change in, health policy or standard of care.

The NIDDK's *HALT-C* (**H**epatitis C **A**ntiviral **L**ong-Term **T**reatment against **C**irrhosis) trial is a multi-center, randomized controlled study designed to determine if long-term treatment with peginterferon in previous non-responders with advanced hepatic fibrosis can prevent cirrhosis and reduce the risk of developing end-stage liver disease and hepatocellular carcinoma. Antiviral therapy with peginterferon and ribavirin leads to a sustained virological response in approximately half of patients with chronic hepatitis C. Patients who achieve a sustained loss of hepatitis C virus (HCV) usually have marked improvements in liver histology. Lesser but important degrees of improvement in liver histology also occur in interferon-treated patients who fail to achieve a virological response. Furthermore, data from a recent controlled study suggest that continuing interferon in non-responder patients can maintain the histological improvements. Interferon therapy may also reduce the incidence of hepatocellular carcinoma and improve survival in patients with cirrhosis.

In this trial, non-responders to previous treatment with interferon, interferon and ribavirin, or peginterferon were retreated initially with peginterferon alfa-2a (Pegasys, Roche Pharmaceuticals) in a dose of 180 mcg/week and ribavirin in a dose of 1,000 to 1,200 mg/day for 24 weeks (the lead-in phase). Those who became HCV RNA negative were continued on treatment for 48 weeks, whereas those who remained HCV RNA positive entered the formal protocol and were randomly assigned either to continue treatment with peginterferon alfa-2a alone (90 mcg/week) for an additional 42 months or be followed without treatment. Patients are followed with outpatient visits and blood tests every three months. Liver biopsies are performed at baseline and after 2 and 4 years of treatment.

The study goal to randomize 900 patients into the controlled phase was achieved in June 2003. This sample size will provide 90% power to detect a decrease in the annual rate of development of cirrhosis or its complications from 6% per year among controls to 3% per year in those treated.

Primary outcome variables to be assessed in the 2 groups of patients include progression to cirrhosis on liver biopsy, development of hepatic decompensation, development of hepatocellular carcinoma, and death.

Secondary outcomes include quality of life and serious adverse events.

The study is being conducted at 10 clinical centers in the United States, with the support of a virology laboratory and a data-coordinating center. The study is also supported by a clinical research and development agreement with Roche Pharmaceuticals and is cosponsored by the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Center on Minority Health and Health Disparities.

NASH Clinical Research Network—Nonalcoholic fatty liver disease is one of the most common causes of liver disease in the United States, and its prevalence appears to be increasing. In surveillance studies of chronic liver disease, nonalcoholic fatty liver disease is the third most common diagnosis, accounting for 10% of new cases. The spectrum of nonalcoholic fatty liver disease includes simple steatosis, steatosis with inflammation, and what is currently referred to as nonalcoholic steatohepatitis (NASH). The differentiation of simple steatosis from NASH requires liver biopsy, as there are no laboratory tests for this distinction. The diagnosis of NASH requires the presence of fat, inflammation, and centrolobular (zone 3) ballooning degeneration with either pericellular fibrosis or

Mallory bodies. This distinction is important because NASH is believed to be a progressive liver disease that can lead to cirrhosis and even hepatocellular carcinoma, whereas simple steatosis or fatty liver is usually non-progressive and benign. In some cases, however, patients with steatosis alone are later found to develop full-blown NASH. Clinical features, serum aminotransferase elevations, and hepatic imaging studies showing changes suggestive of fatty liver are not adequate alone or in combination to distinguish simple steatosis from NASH. These considerations make it difficult to evaluate the natural history and course of nonalcoholic fatty liver disease or better define the need for therapy or intervention. The causes of NASH are not well defined, but it typically occurs in association with obesity, insulin resistance or type 2 diabetes, and hyperlipidemia, suggesting that fatty liver and NASH are hepatic manifestations of the dysmetabolic syndrome, and might better be referred to as metabolic steatohepatitis (MESH). The lack of clear understanding of the pathogenesis of NASH, its natural history, prognostic features, and treatment all underscore the need for clinical and basic research into this important liver disease.

In response to these needs, NIDDK initiated a request for applications (RFA) to create a multicenter study on the natural history, pathogenesis, and therapy of NASH. The RFA was published in February 2001, and 8 clinical centers and a data coordinating center were awarded in September 2002. Cofunding to allow for expansion of the pediatric component was provided by the National Institute of Child Health and Development (NICHD). The NASH Network will create both a prospective and retrospective database of adult and pediatric cases of nonalcoholic fatty liver disease that will be evaluated and followed prospectively in a standardized fashion. A pathology committee has proposed a standardized system for histological grading and staging and has initiated studies of its reliability and reproducibility. The Network has also developed plans to conduct randomized controlled trials of promising therapies of NASH, both in children and in adults. These studies will focus initially on use of insulin-sensitizing agents and vitamin E. Endpoints of therapy will be based on histological improvements using the standardized grading and staging systems that are currently being refined. An important component of the NASH Clinical Research Network is to develop a cohort of patients and a collaborative group of clinical and basic researchers to generate hypotheses and develop ancillary studies using the resources of the database. These ancillary studies may be in the area of laboratory research or clinical investigation and will focus on pathogenesis and determinants of progression and severity.

Biliary Atresia Clinical Research Consortium—Neonatal liver disease affects 1 in 2,500 liver births, and its major cause is biliary atresia. At present, biliary atresia is the single most common reason for liver transplantation in children and is a major challenge for early detection, diagnosis, and management. At the same time, the underlying cause of biliary atresia is unclear. The disease is congenital but does not appear to be familial or inherited. Various hypotheses have been advanced to explain the occurrence of biliary atresia, but none have proven to be true or to lead to a practical means of early detection, diagnosis, treatment, or prevention. Because biliary atresia and other forms of neonatal liver disease are rare, no single referral center in North America cares for enough new patients each year to allow for intensive analysis of etiology and risk factors or to critically assess novel means of diagnosis or treatment. For these reasons, NIDDK established a Biliary Atresia Clinical Research Consortium (BARC). The consortium is charged with establishing and maintaining the infrastructure for accruing sufficient numbers of biliary atresia and neonatal hepatitis patients to perform adequately powered clinical studies. The overall goal of this consortium is to gather clinical and biochemical data and adequate numbers of serum, tissue, and DNA samples in a prospective manner to facilitate research and generate new hypotheses and test existing hypotheses on the pathogenesis and optimal diagnostic and treatment modalities of these disorders. It is also hoped that the establishment of this consortium and the serum and tissue bank will stimulate other scientists to develop an interest in investigating the etiology and pathogenesis of these disorders and collaborate with the consortium, with serum and tissue being made available for appropriate studies. The study is

funded by NIDDK and the Office of Rare Disorders. At present, BARC consists of 9 liver disease Clinical Centers and a Data Coordinating Center.

Adult-to-Adult Living Donor Liver Transplantation Cohort Study—Liver transplantation is now the standard of care for patients with end-stage liver disease. At present, more than 4,500 liver transplants are done yearly. Unfortunately, more than 18,000 patients await liver transplantation, and in recent years, the waiting list has continued to grow. As a consequence, the numbers of patients dying on the liver transplant waiting list has grown. The introduction of the MELD system was designed to assign livers to the patients in most critical need for transplantation and, thereby, decrease the waiting list mortality. While this approach may have been partially successful, the continued shortage of cadaveric livers and continued growth of demand for liver transplantation will mean that the mortality rate on the waiting list will continue to be high.

Among possible remedies to the shortage of cadaveric livers for transplantation, living donor liver transplantation is perhaps the most practicable, but also the most controversial. Living donor liver transplantation has become widely accepted for pediatric patients. For children, the left lobe of an adult liver is adequate for transplantation, and left-lobe living donor liver transplantations (particularly from parent to child) have been done successfully for more than a decade. For adults, transplantation of a left lobe of the liver (approximately 20-30% of the liver mass) is usually inadequate to support life, particularly in a patient already suffering from end-stage liver disease. Transplantation of the right lobe (50-60% of the liver mass) can be successful in adults, but the donor operation is accordingly more extensive and more life-threatening. Adult-to-adult living donor liver transplantation was first accomplished in the late 1990s and was introduced into the United States in 1997 and now accounts for approximately 5% of all liver transplants done in the United States. Nevertheless, the donor operation in adult-to-adult liver transplantation is challenging and potentially dangerous.

To address the issues of proper use, relative risks, and potential benefits of adult-to-adult living donor liver transplantation, NIDDK established a multicenter clinical cohort study. The "Adult-to-Adult Living Donor Liver Transplantation Cohort Study" (A2ALL) consists of 9 liver transplant centers experienced in performing living donor liver transplantation and a data coordinating center responsible for directing and maintaining an infrastructure of a clinical database on patients. The primary goal of A2ALL will be to provide valuable information on the outcomes of living donor liver transplantation. The cohort study will follow both donors and recipients before and after the liver transplant operation to assess clinical outcomes and quality of life. This information is needed to aid decisions made by physicians, patients, and potential donors.

Hepatotoxicity Network—Liver injury due to medications is one of the most common causes of acute liver disease and jaundice. Importantly, the mortality rate of hepatic idiosyncratic drug reactions is quite high, and over half of cases of acute liver failure in the United States are due to medications. Elucidation of the mechanisms of hepatic drug injury, however, is often difficult. Drug-induced liver disease is typically unpredictable, idiosyncratic, and rare. Most of the medications that cause acute liver injury in humans do not produce injury in experimental animals. Attribution of acute liver injury to a medication is frequently difficult: the patient with hepatotoxicity often has multiple other risk factors for liver disease, may be on many potentially hepatotoxic drugs, and may not present until the injury resolved. Drug-induced liver injury is also quite variable in clinical expression. Patterns of injury mimic virtually all other forms of liver disease, including acute viral hepatitis, autoimmune liver disease, bland cholestasis, mixed cholestatic-hepatic syndromes, acute cholangitis, microvesicular steatosis with lactic acidosis, alcohol-like steatohepatitis, and venoocclusive disease. Finally, drugs that cause hepatotoxicity are usually withdrawn from use and are no longer available for study.

Despite the clinical significance of drug-induced liver injury, this form of liver disease is a relatively unstudied area of research. Part of the difficulty in studying drug-induced liver disease is the absence of a sufficient cohort of well-characterized patients in whom to carry out clinical, genetic, immunological, and biochemical investigation. To help develop a prospective database on drug-related hepatotoxicity, NIDDK has established a Hepatotoxicity Clinical Research Network. The Network consists of 5 interactive clinical centers and a data coordinating center. The objective of the Network is to develop standardized definitions and instruments to identify and characterize bone fide cases of drug-induced liver injury. Researchers could then analyze the epidemiology and clinical spectrum of hepatotoxicity and identify cases of medication-induced liver disease prospectively. They could also collect biological samples to study the pathogenesis of hepatotoxicity using biochemical, serological, and genetic techniques. The Network will be expected to collaborate with other investigators in the areas of hepatocyte biology and cell injury as well as pharmacokinetics and pharmacogenetics. A respository will be established for storage of serum, tissue, and DNA samples. The Network will be funded as a pilot phase (3 years) which, if successful, will be extended by future RFAs.

Obesity Research Programs

The ***Bariatric Surgery Clinical Research Consortium*** will provide infrastructure for and facilitate coordinated clinical, epidemiological, and behavioral research in the field of bariatric surgery through the cooperative development of common clinical protocols and a bariatric surgery database. The Consortium will also provide the preliminary data and background for further investigator-initiated research. Consortium goals include a greater understanding of the risks and benefits of bariatric surgery as a treatment; the standardization of definitions and data collection instruments to enhance the ability to provide meaningful evidence-based recommendations for patient evaluation, selection, and follow-up care; basic and clinical studies to explore the mechanisms by which surgery affects obesity-related co-morbid conditions, energy expenditure, nutrient partitioning, appetitive behaviors, and psychosocial factors. Four to six clinical centers and a data coordinating center were funded in September 2003.

The Program on ***Genetics and Genomics of Obesity*** supports research to identify genes that influence obesity and related anatomical, physiological, and behavioral traits such as body fat composition and distribution, metabolic rate, energy balance, food consumption and preference, and physical activity levels, as well as research on patterns of gene expression associated with these traits, and mechanisms of regulation of these patterns. The Program supports research on humans as well as model organisms, encouraging both genome-wide and candidate-gene based approaches exploiting naturally occurring genetic variation as well as artificially induced mutations. Typical approaches include genetic linkage, association, and linkage-disequilibrium studies, QTL mapping, phenotype- and gene-driven mutagenesis screens, and macro- and microarray-based surveys of gene expression.

The ***Obesity and Eating Disorders Program*** emphasizes support of investigator-initiated basic and clinical research relating to biomedical and behavioral aspects of obesity and eating disorders, particularly binge eating disorder and its relationship to obesity. Areas of research interest include investigations of factors that affect food choices, food intake, eating behavior, appetite, satiety, body composition, nutrient partitioning, physical activity, and energy regulation. The roles of neural and hormonal factors from the molecular to the whole-animal/human level are encompassed within this program if the primary goal of the investigations is to examine their role in the development or maintenance of obesity. The physiological and metabolic consequences of weight loss or weight gain, the effects of exercise and diet composition on appetite and weight control, and the individual variability in energy utilization and thermogenesis are contained within the specific research interests of this program. Investigations incorporating improved methods for assessment of body composition,

examination of health risk factors with specific degrees of obesity or body composition, and determination of the effect of exercise on body composition also are supported.

The ***Obesity Prevention and Treatment Program*** supports research that focuses on the prevention and treatment of overweight and obesity in humans. Prevention includes primary and secondary approaches to prevent the initial development of overweight/obesity through control of inappropriate weight gain and increases in body fat, weight maintenance among those at risk of becoming overweight, and prevention of weight regain once weight loss has been achieved. Treatment includes clinical trials evaluating approaches to lose weight or maintain weight loss, including but not limited to behavioral, pharmacologic, and surgical approaches. This program also includes environmental, policy-based, and population-based approaches to the prevention and treatment of obesity.

Look AHEAD: Action for Health in Diabetes is a clinical trial recruiting 5,000 obese individuals with type 2 diabetes into an 11.5-year study that will investigate the long-term health consequences of interventions designed to achieve and sustain weight loss. The primary outcome of the trial is cardiovascular events: heart attack, stroke, and cardiovascular death. The study also will examine the impact of interventions on cardiovascular risk factors, diabetes control, cost effectiveness, quality of life, and a number of additional measures. The Obesity Special Projects program also administers ancillary studies to Look AHEAD. Recruitment for Look AHEAD was expected to end at most centers by the end of 2003.

As a means of encouraging a multidisciplinary approach to obesity and nutrition research, the Division supports ***Obesity/Nutrition Research Centers (ONRC)***. The goal of an ONRC is to help coordinate and strengthen support for research activities primarily by providing funds for core facilities and associated staff that serve the various projects on a shared basis. This approach ensures that an ONRC has multiple sponsors, both Federal and non-Federal, and thereby reduces the likelihood that the ONRC will become unduly dependent on any one source of funds for its continued operation. The specific objectives of an ONRC include efforts to:

- Create or strengthen a focus in biomedical research institutions for multidisciplinary research in obesity and nutrition
- Develop new knowledge concerning the development, treatment, and prevention of obesity and eating disorders
- Understand control and modulation of energy metabolism
- Understand and treat disorders associated with abnormalities of energy balance and weight management such as in anorexia nervosa, AIDS, and cancer
- Strengthen training environments to improve the education of medical students, house staff, practicing physicians, and allied health personnel about these conditions

To accomplish the overall goal of these centers, the applicant's institution must have an on-going program of excellence in biomedical research related to the study of obesity and associated disorders. Due to a restriction in the number of core center grants that can be supported, new center grant proposals will be accepted only in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts.

Nutrition Sciences Programs

The ***Nutrient Metabolism Program*** supports basic and clinical studies related to the requirement, bioavailability, and metabolism of nutrients and other dietary components at the organ, cellular, and subcellular levels in normal and diseased states. Specific areas of research interest include:

- Understanding the physiologic function and mechanism of action/interaction of nutrients within the body
- Nutrient influence on gene regulation and expression
- Metabolism and function of nutrient antioxidants
- Effects of environment, heredity, stress, drug use, toxicants, and physical activity on problems of nutrient imbalance and nutrient requirements in health and disease
- Specific metabolic considerations relating to alternative forms of nutrient delivery and use, such as total parenteral nutrition
- Research to improve methods of assessing nutritional status in health and disease

The ***Clinical Trials in Nutrition Program*** supports clinical research on nutrition and eating disorders, focusing on metabolic and/or physiologic mechanisms. Small clinical studies (pilot), planning grants, or phase III clinical trials may be appropriate to this program. The small clinical studies should focus on research that is innovative and/or potentially of high impact. They should lead to full-scale clinical trials. Please see the current program announcement http://grants1.nih.gov/grants/guide/pa-files/PAR-01-056.html for small grants for clinical trials. Phase III clinical trials usually are multi-center and involve several hundred human subjects that are randomized to two or more treatments, one of which is a placebo. The aim of the trial is to provide evidence for support of, or a change in, health policy or standard of care.

A ***Clinical Nutrition Research Unit (CNRU)*** is an integrated array of research, educational, and service activities focused on human nutrition in health and disease. It serves as the focal point for an interdisciplinary approach to clinical nutrition research and for the stimulation of research in areas such as improved nutritional support of acutely and chronically ill persons, assessment of nutritional status, effects of disease states on nutrient needs, and effects of changes in nutritional status on disease. Funding for the CNRU program, which began in 1979, is provided through the core center grant mechanism. Due to a restriction in the number of core center grants that can be supported, new center grant proposals will be accepted only in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts.

Other Programs

- Conferences See http://www3.niddk.nih.gov/fund/other/conferences.shtml
- Small Business Innovation Research (SBIR) See http://www2.niddk.nih.gov/Funding/SmallBusiness/NIH_SBIR_STTR+Program.htm
- Small Business Technology Transfer (STTR) See http://www2.niddk.nih.gov/Funding/SmallBusiness/NIH_SBIR_STTR+Program.htm
- Training http://www2.niddk.nih.gov/Funding/TrainingCareerDev/
- Career Development

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/DDN/

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Overview of the Division of Kidney, Urologic, and Hematologic Diseases

The Division supports research on diseases of the kidney, genitourinary tract, and blood and blood-forming organs, and on the fundamental biology relevant to these organ systems. It funds training and professional development of investigators in disciplines critical for research in these areas.

Kidney Research

The ***Basic Renal Biology Program*** supports research on normal development, structure, and function of the kidney. Areas of emphasis include glomerular function and cell biology, transport physiology and structure-function analysis of transport proteins, and integrated regulation of solute and water excretion. The program supports investigation of adverse effects of nephrotoxic drugs and environmental toxins and mechanisms of hypoxic renal cell injury.

A major area of strength is studies examining intracellular signal transduction for renal hormones and growth factors. In addition to study on mammalian systems, investigation is supported on transport function and development and genomic analysis of membrane transport proteins using simple systems such as bacteria, *C. elegans,* and zebrafish.

The ***Chronic Renal Diseases Program*** supports basic and clinical studies on the etiology, prevention, diagnosis, and treatment of chronic renal diseases. Disease categories receiving particular emphasis include analgesic nephropathy, polycystic kidney disease, diabetic nephropathy, glomerulonephritis and other immune disorders of the kidney, hypertensive nephrosclerosis, and HIV nephropathy. A major interest in this program is renal diseases that affect children and the effects of chronic renal insufficiency on growth and development of children.

The ***End-Stage Renal Disease Program*** supports investigation on the pathogenesis of the uremic state, on end-stage renal disease treatment by peritoneal and hemodialysis, and on nutrition in renal disease. Investigation on renal transplantation is supported with particular emphasis on nonimmunological renal injury and on methods of increasing organ availability, particularly in minority populations.

The ***Diabetic Nephropathy Program*** supports investigation into the pathogenesis, prevention, and treatment of the kidney disease associated with diabetes mellitus. One major area of emphasis is the identification of genes associated with familial clustering of diabetic kidney disease, through sponsorship of the FIND consortium.

The ***Pediatric Nephrology Program*** supports basic and clinical research on the causes, treatments, and prevention of kidney diseases of children. Research efforts focus on inherited and congenital renal diseases; kidney disease of diabetes mellitus; IgA nephropathy; and kidney disease and hypertension, which starts in early childhood.

The ***Renal Epidemiology Program*** supports investigation into the incidence and prevalence of renal diseases, the factors associated with increased mortality and co-morbidity, and cost-benefit assessment of prevention and treatment strategies.

The ***U.S. Renal Data System (USRDS),*** an information resource for the epidemiology of end-stage renal disease, is supported through this program. USRDS investigation of cost factors in dialysis care is co-funded with the Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration.

Urology Research

The ***Basic Urology Program*** supports basic research on the normal and abnormal development, structure, and function of the genitourinary tract. A major area of interest is investigation of the biology of bladder cells, including studies on transport properties, effects of obstruction on patterns of protein expression, and examination of interactions between urinary pathogens and cells of the urinary tract. The program on prostate biology has particular strengths in investigation of prostate cell growth and mechanisms of growth factor signal transduction.

The ***Clinical Urology Program*** focuses on research that will increase the knowledge of etiology, diagnosis, pathophysiology, therapy, and prevention of major pediatric and adult urological disorders. Non-malignant disorders of the bladder and prostate, including benign prostatic hyperplasia, interstitial cystitis, urinary tract infections, urinary incontinence, and urolithiasis are areas of emphasis, as are the effects of systemic diseases such as diabetes mellitus, spinal cord injury, and multiple sclerosis on these organs. In addition, the program supports studies of diagnostic and therapeutic modalities such as shock-wave and laser lithotripsy, urolithiasis inhibitors, bladder substitution procedures and devices, and prostate growth inhibitor and reduction therapies.

The ***Urologic Diseases Epidemiology Program*** has a major emphasis on developing a source of epidemiological information that may further understanding of natural history, risk factors, and health resource utilization for urologic conditions. Plans are to collect and analyze new and existing data on incidence, prevalence, morbidity, mortality, and health resource utilization associated with various urologic conditions of high public health importance. The information will be presented in a planned publication tentatively titled "Urologic Diseases in America."

Hematology Research

The ***Hematology Program*** supports research into the fundamental processes underlying the normal and pathologic function of blood cells and the reticuloendothelial system. Major areas of interest include:

- Genetic regulation of hemoglobin and other proteins of the blood
- Acquired and inherited anemias
- Cell membrane composition and regulatory processes
- Iron metabolism, storage, and transport
- Hematopoiesis and its regulation by growth factors, including erythropoietin
- Transcription and signaling factors such as the JAK/STAT pathway involved in hematopoietic cell differentiation
- Immunohematology
- Hematopoiesis, hematopoietic stem cell biology, and the expression of differentiation potential of hematopoietic stem cells
- Stem cell plasticity and the cellular, molecular, and genetic mechanisms that allow cells to express plasticity

Emphasis is on the application of fundamental knowledge to current issues such as gene transfer therapy and bone marrow transplantation, and disorders such as sickle cell anemia, thalassemia, hemochromatosis, iron deficiency anemia, thrombocytopenia, and hemolytic anemia.

The ***Chelator Therapy Program*** supports development of new iron chelating drugs for the treatment of transfusion iron overload, such as in Cooley's anemia, sickle cell disease, and other instances of iron overload. A safe and inexpensive orally active iron chelator that effectively promotes iron excretion is needed urgently, since the only currently available drug, desferrioxamine B, is expensive and is painful and cumbersome to administer, leading to widespread non-compliance among the

young adult patient population. Pre-clinical toxicity studies of potential iron chelating drugs are performed under the contract mechanism. Grant support is offered for basic research on the kinetics of iron chelation, the identity of the iron pools addressed, and ways to enhance the chelating activity and reduce the toxicity of known iron chelators.

The ***Hematopoietic Lineage Genomics Anatomy Program***—This program has been initiated to merge the fields of hematopoietic cell biology, including erythroid cell physiology, with bioinformatics. The combination of these two fields will: 1) advance the ability to catalog and monitor genes that are expressed during normal and variant hematopoietic cell differentiation, 2) facilitate a more comprehensive understanding of the dynamics of molecular events that occur during differentiation, and most importantly, 3) develop a quantitative model that incorporates known gene expression data into a description of a red blood cell. This model could then be used to test novel expression patterns as they are discovered and also be used as a scaffold from which to devise models for other tissue and organ development.

Genomics Research

The ***Genomics Research Program*** encompasses research on genomics and related technologies in the study of kidney, genitourinary tract, and blood and blood-forming organs. This program also supports model organism genomics research, including the development of genetic tools for high-throughput functional genomics studies. One major programmatic area is the leadership of a major trans-NIH initiative to develop genomics of zebrafish, Danio rerio.

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/KUH/

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Program Director of Kidney and Urology Training Programs/Director of Basic PKD Research	Dr. Tracy Rankin	2 Democracy Plaza, Rm. 623	(301) 594-7717 rankint@mail.nih.gov
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National Kidney Disease Education Program, Associate Director	Eileen Newman	Building 31, Rm. 9A-06	(301) 435-8116 newmaneileen@niddk.nih.gov
Clinical Trial Specialist	Dr. Yining Xie	2 Democracy Plaza, Rm. 634	(301) 594-7713 xieyi@niddk.nih.gov

Overview of the Division of Nutrition Research Coordination

The Division of Nutrition Research Coordination (DNRC) advises the National Institutes of Health (NIH) Director and others on nutrition research issues and works with the NIH organizational components to coordinate nutrition research and research training initiatives. Since the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the lead institute for nutrition research at NIH, this NIH-wide division is located within NIDDK.

DNRC also represents NIH and provides liaison at DHHS and interagency level on various committees on nutrition research and policy issues such as the Interagency Committee on Human Nutrition Research and Nutrition Policy Board. Located within the DNRC is the NIH Nutrition Coordinating Committee (NCC) which operates as an NIH-wide forum to review, stimulate, and encourage the support of nutrition research and training to better define the role of nutrition in the promotion and maintenance of health and in the prevention and treatment of disease. The NCC also plays a key role in the development of nutrition research policy at the NIH. Further, the DNRC maintains the Human Nutrition Research Information Management (HNRIM) system. HNRIM is a searchable database of nutrition research and research training activities supported by the federal government. Data for the system is prepared and submitted by participating agencies, and is updated annually.

Website: http://dnrc.nih.gov/

How To Contact Us

Division of Nutrition Research Coordination (DNRC)

Building	**U.S. Postal Address**		**UPS, Fedex, etc.**
2 Democracy Plaza	6707 Democracy Blvd., Rm. 679, MSC 5461, Bethesda, MD 20892-5450		6707 Democracy Blvd., Rm. 679, Bethesda, MD 20817 (301) 594-8822
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Program Analyst	Karen S. Regan	2 Democracy Plaza, Rm. 640	(301)-435-6199 Karen_Regan@nih.gov

Funding Mechanisms (Activity Codes) Supported by NIDDK

Brief Overview

An Activity Code is a three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). General categories include:

- F -- fellowships
- K -- career development awards
- N -- research contracts
- P -- program project and research center grants
- R -- research project grants
- S -- research-related programs
- T -- training grants
- U -- cooperative agreements
- Y -- interagency agreements

Extramural research activities are divided into three main mechanisms: grants, cooperative agreements, and contracts. A mechanism is the type of funding instrument used at the NIH. In general, with grants (all activity codes other than "N" or "U"), investigators are responsible for developing the concepts, methods, and approach for a research project. With contracts ("N" series), the DHHS awarding unit is responsible for establishing the detailed requirements. With cooperative agreements ("U" series), both the awarding unit and the recipient have substantial responsibility. Programs are areas within the funding mechanisms (for example, research, training, fellowships, and cooperative agreements). Activity codes identify categories applied to various mechanisms.

For NIH-wide activity codes and definitions beyond the NIDDK codes listed below, go to IMPAC Activity Codes, Organization Codes, and Definitions Used In Extramural Programs (Tables 2-4) http://grants.nih.gov/grants/funding/ac.pdf. Table 3 is the one most relevant to NIDDK. Also see the Types of Grant Programs page (http://grants.nih.gov/grants/funding_programs.htm) to search activity codes and for more information on selected grant programs.]

Special NIH-Wide Programs

DP1 **NIH Director's Pioneer Award** (NDPA) (Roadmap program)
To support individuals who have the potential to make extraordinary contributions to medical research. The NDPA is not renewable.

DP2 **NIH Director's New Innovator Awards** (Roadmap program)
To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

DP3 **Type 1 Diabetes Targeted Research Award**
To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

Fellowship Programs

F 31 **Predoctoral Individual National Research Service Award**
To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

F 32 **Postdoctoral Individual National Research Service Award**
To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

F 33 **National Research Service Awards for Senior Fellows**
To provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

Research Career Programs

K 01 **Research Scientist Development Award - Research & Training**
For support of a scientist, committed to research, in need of both advanced research training and additional experience.

K 08 **Clinical Investigator Award (CIA)**
To provide the opportunity for promising medical scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research aspects of categorical areas applicable to the awarding unit, and aid in filling the academic faculty gap in these shortage areas within health profession's institutions of the country.

K 12 **Physician Scientist Award (Program) (PSA)**
For support to a newly trained clinician appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

K 18 **The Career Enhancement Award**
To provide either full-time or part-time support for experienced scientists who wish to broaden their scientific capabilities or to make changes in their research careers by acquiring new research skills or knowledge. Career enhancement experiences supported by this award should usually last no more than one year.

K 22 **Career Transition Award**
To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial period involving and intramural appointment at the NIH and a final period of support at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator in order to sustain or promote a successful research career.

K 23 **Mentored Patient-Oriented Research Career Development Award**
To provide support for the career development of investigators who have made a commitment of focus their research endeavors on patient-oriented research. This mechanism provides support for a 3 year minimum up to 5 year period of supervised study and research for

clinically trained professionals who have the potential to develop into productive, clinical investigators.

K 24 **Midcareer Investigator Award in Patient-Oriented Research**
To provide support for the clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators.

K 25 **Mentored Quantitative Research Career Development Award**
To engender and foster such activities by supporting the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have made a commitment to focus their research endeavors on behavioral and biomedical research (basic or clinical). This mechanism is aimed at research-oriented scientists with experience at the level of junior faculty (e.g., early to mid-levels of assistant professor or research assistant professor ranks). This award provides support for a period of mentored study and research for professionals with such backgrounds who have the potential to integrate their expertise with biomedicine and develop into productive investigators.

Examples of quantitative scientific and technical backgrounds outside of biology or medicine considered appropriate for this award include, but are not limited to: mathematics, statistics, computer science, informatics, physics, chemistry, and engineering.

K 30 **Clinical Research Curriculum Award (CRCA)**
The CRCA is an award to institutions and is intended to stimulate the inclusion of high-quality, multi-disciplinary didactic training as part of the career development of clinical investigators. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research to support or expand their programs or to improve the quality of instruction.

K 99/ **NIH Pathway to Independence Award (PI)**
R 00 To provide an opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. The primary purpose of the Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The initial phase (K99 Career Transition Award) provides 1-2 years of mentored support for highly motivated, advanced postdoctoral research scientists. The second phase (R00 Research Transition Award) provides 1-3 years of independent research support contingent on securing an independent research position. Award recipients will be expected to compete successfully for independent R01 support from the NIH during the R00 research transition award period

Extramural Loan Repayment Program

L 30 **Loan Repayment Program for Clinical Researchers**
To provide for the repayment of the educational loan debt of qualified health professionals involved in clinical research. Qualified health professionals who contractually agree to conduct qualified clinical research are eligible to apply for this program.

L 40 **Loan Repayment Program for Pediatric Research**
To provide for the repayment of the educational loan debt of qualified health professionals involved in research directly related to diseases, disorders, and other conditions in children.

Qualified health professionals who contractually agree to conduct qualified pediatric research are eligible to apply for this program.

Research and Development-Related Contracts

N 01 **Research and Development Contracts**
To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

N 02 **Resource and Support Contracts - Awarded in the ICD**
To support intramural and extramural station support needs. This activity also includes the provision of resources to intramural research programs.

N 41 **Small Business Technology Transfer (STTR) Contracts - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

N 42 **Small Business Technology Transfer (STTR) Contracts - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

N 43 **Small Business Innovation Research (SBIR) Contracts- Phase I**
To support project, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s). These contracts may be made only with small businesses.

N 44 **Small Business Innovation Research (SBIR) Contracts - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be made only to small businesses.

Research Program Projects and Centers

P 01 **Research Program Projects**
For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P 20 **Exploratory Grants**

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P 30 **Center Core Grants**
To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant is integrated with the center's component projects or program projects, though funded independently from them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects.

P 50 **Specialized Center**
To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

P 60 **Comprehensive Center**
To support a multipurpose unit designed to bring together into a common focus divergent but related facilities within a given community. It may be based in a university or may involve other locally available resources, such as hospitals, computer facilities, regional centers, and primate colonies. It may include specialized centers, program projects and projects as integral components. Regardless of the facilities available to a program, it usually includes the following objectives: to foster biomedical research and development at both the fundamental and clinical levels; to initiate and expand community education, screening, and counseling programs; and to educate medical and allied health professionals concerning the problems of diagnosis and treatment of a specific disease.

Research Projects

R 01 **Research Project**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R 03 **Small Research Grants**
To provide research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies which are generally for preliminary short-term projects and are non-renewable.

R 13 **Conference**
To support recipient sponsored and directed international, national or regional meetings, conferences and workshops.

R 15 **Academic Research Enhancement Awards (AREA)**

To support small scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to $75,000 for direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R 18 **Research Demonstration and Dissemination Projects**
To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R 21 **Exploratory/Developmental Grants**
To encourage the development of new research activities in categorical program areas. (Support generally is restricted in level of support and in time.)

R 24 **Resource-Related Research Projects**
To support research projects that will enhance the capability of resources to serve biomedical research.

R 25 **Education Projects**
For support to develop and/or implement a program as it relates to a category in one or more of the areas of education, information, training, technical assistance, coordination, or evaluation.

R 33 **Exploratory/Developmental Grants Phase II**
The R33 award is to provide a second phase for the support for innovative exploratory and development research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under R33.

R 34 **Clinical Trial Planning Grant**
To provide support for the initial development of a clinical trial, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

R 37 **Method to Extend Research in Time (MERIT) Award**
To provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT award. Program staff and/or members of the cognizant National Advisory Council/Board will identify candidates for the MERIT award during the course of review of competing research grant applications prepared and submitted in accordance with regular PHS requirements.

R 41 **Small Business Technology Transfer (STTR) Grants - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R 42 **Small Business Technology Transfer (STTR) Grants - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

R 43 **Small Business Innovation Research (SBIR) Grants - Phase I**

To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

R 44 **Small Business Innovation Research (SBIR) Grants - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. SBIR Phase II are considered ˜Fast-Track˜ and do not require National Council Review.

R 56 **High Priority, Short Term Project Award**
To provide limited interim research support based on the merit of a pending R01 application while applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Interim funded ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Research-Related Programs

S 06 **Minority Biomedical Research Support - MBRS**
To strengthen the biomedical research and research training capability of ethnic minority institutions, and thus establish a more favorable milieu for increasing the involvement of minority faculty and students in biomedical research.

SC 1 **Research Enhancement Award**
Individual investigator-imitated research projects aimed at developing researchers at minority-serving institutions (MSIs) to a stage where they can transition successfully to other s extramural support (R01 or equivalent).

SC 2 **Pilot Research Project**
Individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for a more ambitious research project.

SC 3 **Research Continuance Award**
Individual investigator-initiated research projects for faculty at MSIs to conduct research of limited scope in environments with limited research infrastructure/facilities.

Training Programs

T 32 **Institutional National Research Service Award**
To enable institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas.

T 35 **NRSA Short-Term Research Training**
To provide individuals with research training during off-quarters or summer periods to encourage research careers and/or research in areas of national need.

T90 **Interdisciplinary Research Training Award**
To support comprehensive interdisciplinary research training programs at the undergraduate, predoctoral and/or postdoctoral levels, by capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs.

Cooperative Agreements

Note: For all funding mechanisms within this section, substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

U 01 **Research Project--Cooperative Agreements**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U 10 **Cooperative Clinical Research--Cooperative Agreements**
To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and are usually conducted under established protocols.

U 13 **Conference--Cooperative Agreements**
To support international, national or regional meetings, conferences and workshops where substantial programmatic involvement is planned to assist the recipient.

U 19 **Research Program--Cooperative Agreements**
To support a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach. This generally involves the organized efforts of large groups, members of which are conducting research projects designed to elucidate the various aspects of a specific objective. Each project supported through this mechanism should contribute to or be directly related to the common theme of the total research effort. The award can provide support for certain basic shared resources, including clinical components, which facilitate the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence.

U 24 **Resource-Related Research Projects--Cooperative Agreements**
To support research projects contributing to improvement of the capability of resources to serve biomedical research.

U 34 **Multi-Center Clinical Study Implementation Planning Grants**
Clinical Planning Grant Cooperative Agreement—To provide support, substantial Federal programmatic involvement, and technical assistance for the initial development of a clinical trial. Also, it would include the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

U-32 **State-Based Diabetes Control Programs**
Programs in cooperation with State health agencies: To reduce the effect of preventable problems in service delivery to diabetics (such as excess days of hospitalization, high amputation rates, and the effect of insurance policy on securing care), to define the preventable service delivery problems, and to demonstrate improved service delivery to diabetics.

NIH-Wide FY 2009 Funding Policy

Non-Competing Grant Awards under the Current Continuing Resolution

Notice Number: NOT-OD-09-002

Key Dates

Release Date: October 2, 2008

Issued by

National Institutes of Health (NIH), (http://www.nih.gov)

The Department of Health and Human Services (HHS) continues to operate on a continuing resolution (CR) [Public Law 110-329 Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009] that currently extends through March 6, 2009. The CR applies the terms of the FY 2008 appropriations for the period covered by the CR. Until the final FY 2009 appropriation is enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006 - 2008. NIH will consider upward adjustments to these levels after the final appropriation is enacted, but expects institutions to monitor their expenditures carefully during this period.

Additional details will appear at http://grants1.nih.gov/grants/financial/index.htm.

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

Weekly TOC for this Announcement:
http://grants.nih.gov/grants/guide/WeeklyIndex.cfm?WeekEnding=10-03-08

NIH Funding Opportunities and Notices: http://grants.nih.gov/grants/guide/index.html

NIDDK Interim FY 2009 Funding Policy

The Department of Health and Human Services (HHS) is currently operating on a Continuing Resolution (CR). NIDDK has established the following funding policy until the final appropriation is enacted.

Non-competing Continuations (Type 5)

Non-competing continuations (modular and non-modular) will be funded at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This policy does not apply to Fs, Ts, Ks, SBIR/STTRs, and R13s.

NIDDK will consider upward adjustments to this level after the final FY 2009 appropriation is enacted.

Information regarding the NIH policy can be found at this link
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-002.html

After the final FY 2009 appropriation is enacted, information regarding NIDDK's funding policies for this fiscal year will be posted at http://www2.niddk.nih.gov/Funding/Grants/FundingPolicy.htm. What you can expect to find at that time will include information similar to that shown for FY 2008 on the next page.

NIDDK FY 2008 Funding Policy

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is committed to supporting as many meritorious competing research grant applications as possible. Particular priorities are (1) enhancing the ability of new investigators to compete for support in these difficult financial times, and (2) protecting our investment in well established investigators with little or no other significant support (see NIH Guide Notice NOT-OD-08-036 [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-036.html] , NIH Fiscal Policy for Grant Awards – FY 2008).

To maximize our available resources, all grant awards will continue to be subject to programmatic adjustments from the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKDAC) approved levels. These adjustments take into consideration the overall scientific and technical merit of the grant application, the cost of the proposed research, and other resources available for related research projects.

Competing New and Renewal Research Grants

For FY 2008 NIDDK is establishing a nominal "payline" for new (Type 1) and renewal or competing continuation (Type 2) R01 applications of 17th percentile (19th percentile for New Investigator applications). Many if not most R01 applications requesting less than $500,000 direct cost per year and scoring better than the 17th percentile will receive an award. However, NIDDK will exercise discretion and consider portfolio balance, programmatic importance and a number of other of factors in determining precisely which applications are awarded. In addition, as mentioned above, all grant awards will continue to be subject to programmatic adjustments from the NDDK Advisory Council approved levels. It is important to note that these funding levels are applicable for applications to be paid in FY 2008. Many applications submitted in FY 2008 will not be eligible for funding consideration until FY 2009. The funding levels for FY 2009 cannot now reliably be predicted.

NIH FY 2008 policy includes the provision of 3% escalation for future years on competing non-modular RPG awards. Applicants for modular awards are understood to have included inflation in their cost before selecting an appropriate modular total.

Non-competing Continuation Awards

Consistent with the NIH Fiscal Policy for Grant Awards – FY 2008 (NOT-OD-08-036) non-competing modular and non-modular grants (Type 5) of the following mechanisms - R01, R03, R18, R21, R24, R25, R33, R34, R35, R37, and P01 as well as Roadmap RPG awards - will be issued at 98% of their established committed levels. Amounts indicated for future budget periods will be adjusted as well. Non-competing U01, U19, and U24 awards will generally be issued at their established committed levels.

New Investigators

Fostering the success of new investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH. The emphasis NIDDK focuses on new investigators is exhibited in the special consideration given in determining both funding priority and period of support. NIDDK routinely considers new investigator applications for payment, including those that score outside of the normal funding range. Consistent with NIH guidelines articulated in NOT-OD-036, NIDDK will maintain a number of new investigators comparable to the average of the most recent five years. In

addition when possible and appropriate the full period of support recommended for funded new investigator grants will be awarded.

Duration of Grant Support

Competing awards are adjusted to achieve a 4 year average duration for research project grants. Nevertheless, applications from new investigators, initial MERIT awards, MERIT extensions, program project grants, and clinical trial grants are generally awarded for the full length of their recommended project period.

NIDDK Exploratory Research Grant (R21) Program

In response to the advice and recommendations of the NDDK Advisory Council, NIDDK refocused its R21 program in FY 2007 and this focus will remain unchanged in FY 2008. NIDDK uses R21 grants to support projects within its research mission that are:

- Innovative, high pay-off, paradigm-shifting projects
- Novel technology and tool development
- Applications of existing methods, technologies, or conceptual approaches from outside biomedical science to a problem in the NIDDK mission
- Pilot clinical trials or clinical studies

Most projects are not suitable for the R21 mechanism. In considering whether to submit an R21 application investigators should consider the following:

- Projects of limited scope or cost that use widely accepted approaches and methods within established fields are NOT appropriate for an R21 application.
- A proposal designed to generate preliminary data for a longer-term project in a well-established research area is NOT appropriate for an R21 application.
- Applications from new investigators to gather preliminary data for a standard R01 are not appropriate for the R21 mechanism.
- R21 proposals submitted by new investigators will NOT be given special priority for funding. The NIDDK believes new investigators are better served by the R01 award for which they are given special priority. Please see Resources for New Investigators.

The NIDDK will support highly risky projects if the proposed research holds promise for a major advance in biomedical research. Although preliminary data are not required, the applicant should provide evidence of his/her ability to carry out the proposed research project. The success rate of NIDDK R21 applications in the past has been highly variable and differs from the success rate for obtaining R01 awards.

Potential applicants are strongly advised to discuss a prospective proposal with a member of NIDDK Program Staff in order to determine whether it is appropriate to submit as an R21 application.

Program Project (P01) Grant Applications and Applications with budgets greater than $500K

NIDDK has adopted a more stringent funding practice for awarding program project (P01) grants and investigator-initiated grant applications with budgets of $500,000 direct costs in any one year. Prior approval is required before submitting an application for review that requests $500,000 or more in direct costs in any one year. The request to submit such applications must be received at least 6 weeks prior to the proposed submission date. Prior approval is required for renewal and revised applications as well as new applications. Please consult with the appropriate NIDDK program staff and visit the

following site for information on research areas supported by NIDDK: http://www2.niddk.nih.gov/Research/ScientificAreas/.

New (Type 1) program project (P01) applications may request a maximum of $5 million in direct costs over five years, exclusive of the subcontract Facilities & Administrative (F&A) costs. Renewal (competing continuation [Type 2]) program project applications may request up to $6.25 million in direct costs over five years, exclusive of Facilities and Administrative (F&A) costs associated with the subcontract(s). In addition to the caps on the amount requested, P01 awards are subject to administrative adjustment from the Advisory Council approved levels. Additional information regarding the P01 applications and their receipt dates can be found at: http://www.niddk.nih.gov/fund/divisions/DEA/review_branch/P01guidelines.htm

Bridge Support

In cases where a competing renewal application falls near but beyond the nominal payline, NIDDK will continue to consider interim support on a case-by-case basis and provide limited, support in selected cases. The goal is to preserve essential research resources pending the re-review of a revised application. NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect preliminary data in order to submit an improved revised R01 application. In addition to NIDDK's efforts along these lines, NIH will continue to take specific steps using NIH Director's Bridge Awards (see NIH Guide Notice NOT-OD-08-037 " *Announcing the FY 2008 NIH Director's Bridge Awards* ") to buttress investigators whose R01 applications receive review scores near the Institute or Center (IC) nominal payline and who have limited additional support. **Note that applicants may not apply for a NDBA and they may not nominate themselves**.

Resources for New NIDDK Investigators

Statement of NIH Commitment to New and Early Stage Investigators

New investigators are the innovators of the future - they bring fresh ideas and technologies to existing biomedical research problems, and they pioneer new areas of investigation. Entry of new investigators into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise. NIH's interest in the training and research funding of new investigators is understandably deep and longstanding. Over the years, special programs to assist new investigators in obtaining independent research funding have been created. In spite of these concerted efforts, the average age at which an investigator first obtains R01 funding increased by 5 to 6 years between 1980 and 2001. During the doubling of the NIH between FY 1998 and 2003, the number of new R01 investigators increased from about 1,500 to more than 1,680. New Investigators accounted for approximately 25 percent of all competing R01 recipients during this period. After the doubling, the number and percentage of new investigators declined reaching a low of 1,365 in FY 2006 and then responding to renewed NIH efforts, increased in FY 2007 and 2008.

In order to address both the duration of training and to protect the flux of new investigators, the NIH announced a new policy in fiscal year 2009 involving the identification of Early Stage Investigators (ESIs). ESIs are New Investigators who are within 10 years of completing their terminal research degree or within 10 years of completing their medical residency at the time they apply for R01 grants. Applications from ESIs will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator. For additional information on NIH's new policies see http://grants.nih.gov/grants/new_investigators/.

The NIH remains committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. However, the NIH cannot do this alone. Institutions - our partners in this venture - must continue to look for ways to reduce the duration of graduate and postdoctoral training and to find new ways to enable new investigators to compete successfully for extramural funding.

NIDDK is dedicated to providing training and research funding for new investigators working on topics within its mission.

NIH Opportunities

NIH has policies and resources designed to assist new investigators in establishing their research programs and careers. New investigators should check the "New PI" box on the face page of their R01 applications so that they can be given special consideration. Peer reviewers are instructed to focus more on the proposed approach than on the track record and to expect less preliminary data than would be provided by an established investigators. Institute staff pay special attention to applications from new investigators as well. In addition, NIH has piloted a program for rapid turnaround for new investigator applications allowing them to revise and resubmit more quickly.

NIDDK Opportunities

NIDDK has created a number of special new investigator opportunities and Frequently Asked Questions for new investigators. Investigators are encouraged to discuss their ideas with NIDDK program staff as they are planning and preparing their grant application. Check NIDDK scientific

areas of interest to find the right staff members and their contact information. NIDDK training program directors are accessible to anyone interested in one-on-one consultations, and their availability at national meetings is published on the NIDDK web site.

Differential payline – Each year, the NIDDK sets a percentile "payline" for R01 applications based on available funds and the volume of applications. The payline for new investigator grants is 2 percentile points more generous than the regular payline for established investigators. While NIDDK often makes administrative reductions in grant duration, applications from new investigators that fall within the payline are usually awarded the full requested duration.

Second-level review –The NIDDK Advisory Council meets to provide second-level review after the initial round of peer review by Scientific Review Groups (study sections). All new investigator R01 applications within 10 percentile points of the payline receive individual consideration during the second-level review process. This could result in the award of an R01 with a reduced budget or a smaller award such as an R56.

NIH High Priority, Short-Term Project Award (R56) – Although a new investigator cannot apply for this grant mechanism, NIDDK can choose to award a 1- or 2-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect preliminary data in order to submit an improved revised R01 application. During second-level review, new investigators are given special consideration for R56 awards.

Career Development (K) awards – NIDDK has a vigorous Career Award program.

Small grants (R03) awards –NIDDK has several relevant funding opportunities for small grants.

Mentoring workshops – NIDDK regularly holds workshops for recently funded new investigators. NIDDK holds a meeting every 18 months that all of NIDDK K-awardees have the opportunity to attend once during the course of their award to orient them to the NIH and the grants process.

Website: NIDDK has a webpage specifically to assist New Investigators:
http://www2.niddk.nih.gov/Funding/Grants/Resources_NewInvestigators.htm

Role of NIDDK Advisory Council

Established by law and charter, the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meets three times annually to advise the NIDDK about its research portfolio. The Council typically undertakes broad issues of science policy. An important role of the Council is to provide second-level peer review of grant applications that have been scored by scientific review groups. The Council members are an important liaison between the research communities they represent and NIDDK, which supports each community's research efforts.

Who are the Council members?

Members of the Advisory Council are drawn from the scientific and lay communities, are appointed for 4-year terms, and represent all areas within the Institute's research mission. The Council membership consists of 18 voting members, including 12 health or science experts and 6 public members.

Six nonvoting, *ex officio* members provide liaison with higher level agencies or organizations having missions consistent with that of NIDDK, including the Secretary, Department of Health and Human Services (DHHS), and representatives from the Department of Defense, Centers for Disease Control and Prevention, and Department of Veterans' Affairs.

Council's health or science experts contribute technical expertise and an understanding of the needs of the research communities of academia and industry. Council's public representatives impart a perspective of people affected by diseases in NIDDK's research mission.

Each Council member also belongs to one of the three Council subcommittees – Digestive Diseases and Nutrition; Diabetes, Endocrinology, and Metabolic Diseases; and, Kidney, Urologic and Hematologic Diseases, corresponding to NIDDK's extramural programmatic divisions.

A copy of the current Council roster is included in the next section on Advisory Council Logistical documents and online at http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/AdvisoryCouncilRoster.htm.

What does the Council do?

As required by law, chartered advisory committees, including the councils, are part of every NIH institute. NIDDK's Council performs the following four key roles:

- Conducts second-level peer review of grant applications scored by scientific review groups
- Advises NIDDK on broad issues of science policy
- Reviews NIDDK programs
- Clears concepts for Program Announcements (PAs), Requests for Applications (RFAs), and Requests for Proposals (RFPs).

The subcommittees conduct most of the NIDDK Division-specific other business, including the closed-session discussion of grant applications.

What is second-level review?

Second-level review is the assessment of the quality of the initial review of grant applications. The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an

application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote.

Expedited Concurrence of En Bloc Actions. For grant and cooperative agreement applications that have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), excluding those from foreign organizations, a process of expedited concurrence is available. The purpose is to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive, and responsible manner. In this process, the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee consists of the Council Executive Secretary and six members of the NDDKAC. Two members are selected from each subcommittee of the NDDKAC. Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within 7 days of notification of posting is required for expedited concurrence approval.

For the first two Councils—January or February and May or June—expedited review enables NIDDK to fund grants a few weeks after the initial peer review meeting. Because September Council reviews applications for funding in the next fiscal year, applicants approved for funding through expedited review will get their awards after the Institute receives its next year's appropriation.

The NIDDK Director makes final funding decisions based on staff and Advisory Council/Board advice.

What happens at Council meetings?

Council meets in September, January or February, and May or June. Its activities are driven partly by the budget and appropriation cycle. For example, discussions in September reflect the beginning of the fiscal year.

In the morning, the full Council meets in open session to hear updates from the Director, NIDDK, and to discuss items that cut across NIDDK Divisional lines. This may include scientific and administrative topics for discussion, often presented by staff or outside speakers.

In the early afternoon, the three subcommittees meet individually to review applications needing special consideration, discuss selective pay nominations, and recommend MERIT awards. Then, the Director, NIDDK, convenes the full Council for a short, closed meeting to discuss and formally approve subcommittee recommendations for funding grants.

Note: A sample agenda is included in the on Advisory Council Logistical documents. The next meeting's agenda is posted several weeks before each meeting and is available from the Council's home page (http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/). Minutes are also posted and available from the home page.

What is Council's role in concept clearance?

NIDDK seeks Council's advice for long-term planning at an early stage. However, the decision to go forward with an initiative is made by NIDDK, based on scientific and programmatic priorities and on the availability of funds.

Definitions of Special Issues Presented to Council

Program staff must prepare the following types of special issues to present to Council. .

1. **Reinstatement of Research Aims**. Applications for which the division is requesting to reinstate specific aims or research not recommended for support by the study section.

2. **Non-Peer-Reviewed Applications**. Used in some circumstances. Council performs both initial peer review and second-level review functions. Renewal MERIT awards are the most common example.

3. **Deferred Applications**. All Council-deferred applications independent of review results.

4. **Unresolved Appeals.** Formerly called rebuttals. When program staff working with a scientific review officer have been unable to resolve the applicant's concerns, the DEA director reviews the appeal, and staff present it to Council.

5. **Foreign Applications**. Foreign applications a division proposes to award. (Foreign applicants may NOT receive R56-Bridge awards.)

6. **Council Member Applications**. Applications proposed for award where a Council member is PI. A subcommittee other than the one on which the Council member serves reviews these applications.

7. **Human Subjects**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of human subjects.

8. **Biohazards**. Applications proposed for award with unresolved concerns about biohazards.

9. **Use of Animals in Research**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of animals in research.

10. **Minority Recruitment Plans in Institutional Training Grant Applications**. Fundable, meritorious National Research Service Award applications with inadequate plans for minority recruitment. When the study section deems a plan inadequate, options are (1) no special action, pay by priority score; (2) defer payment pending submission and staff approval of a recruitment plan; or (3) defer for study section re-review pending receipt of an acceptable plan.

11. **Inclusion of Women and Minorities as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

12. **Inclusion of Children as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

CHARTER

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

PURPOSE

The Secretary of Health and Human Services (Secretary) is mandated under section 301 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 241), to support, conduct, and encourage research studies, and related activities in the health fields. This mandate is fulfilled in part by the mechanism of research grants-in-aid awarded by the research institutes, centers, and other authorized components of the National Institutes of Health (NIH). In addition, the Secretary is authorized under section 487 of the PHS Act, as amended (42 U.S.C. 288), to support research training through National Research Service Awards. The National Diabetes and Digestive and Kidney Diseases Advisory Council (Council) shall advise, assist, consult with, and make recommendations to the Secretary and the Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, also referred to as "Institute") on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

AUTHORITY

42 U.S.C. 284a, section 406 of the PHS Act, as amended. This Council is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Council shall advise the Secretary; the Assistant Secretary for Health; the Director, NIH; and the Director, NIDDK, on matters relating to the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases.

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for study, investigation, or research developed for diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country, and with the approval of the Director of NIDDK, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public; and with the approval of the Executive Secretary, may call upon special consultants, assemble ad hoc working groups, appoint subcommittees and convene workshops and conferences.

The Council may implement procedures for expediting en bloc Council concurrence of Scientific Review Group recommendations. A member or members may be selected by the Executive Secretary or Chair to provide en bloc concurrence on behalf of the Council. Only those applications that do not require individual consideration shall be included in this expedited process. A report of the en bloc recommendations will be presented at each Council meeting.

STRUCTURE

The Council shall consist of 18 members appointed by the Secretary and 6 nonvoting ex officio members: the Secretary; the Director, NIH; the Director, NIDDK; the Chief Medical Director of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs (or their designees); and the Assistant Secretary for Science and Education, United States Department of Agriculture (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Of the 18 appointed members, 12 shall be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the Institute, particularly representatives of the health and scientific disciplines in the areas of diabetes mellitus, endocrinology, metabolism, digestive diseases, nutrition, nephrology, urology, hematology and public health. Six of the members shall be appointed by the Secretary from the general public and shall include leaders in the fields of public policy, law, health policy, economics, and management. None of these members serve as Representatives. A quorum for the conduct of business by the full Council shall consist of a majority of currently appointed members. A quorum for each subcommittee shall be three members.

Members shall be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Terms of more than two years are contingent upon the renewal of the Council's Charter by appropriate action prior to its expiration. A member who has been appointed for a term of four

years may not be reappointed to this Council before two years from the date of expiration of that member's term of office. If a vacancy occurs among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

The Chair of the Council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NIDDK, to be the Chair. The term of office of the Chair shall be two years.

As necessary, subcommittees may be established by the Executive Secretary or other designated Government official to perform functions within the Council's jurisdiction. The advice/recommendations of a subcommittee must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. Subcommittee members who are not members of the parent committee may attend closed sessions of the parent committee meeting but they may not count towards the quorum of the parent committee and they cannot vote on committee actions. The Department Committee Management Officer shall be notified upon establishment of each standing subcommittee and shall be provided information on its name, membership, function, and estimated frequency of meetings.

The Director, NIDDK, will assign a full-time or permanent part-time NIDDK employee to serve as the Executive Secretary (also known as a Designated Federal Official or government official) of the committee. Management and support services shall be provided by the Division of Extramural Activities, NIDDK.

MEETINGS

Meetings of the full Committee shall be held approximately three times a year at the call of the Executive Secretary or other designated Government official. A Government official shall give advance approval of the agenda and be present at all of the meetings of the Council and its subcommittees.

Meetings shall be open to the public except as determined otherwise by the Secretary of Health and Human Services in accordance with subsection (c) of section 552b of Title 5, U.S.C. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable laws and Departmental policies.

COMPENSATION

Members shall be paid at the rate of $200 per day, plus per diem and travel expenses, as authorized by section 5703, Title 5 U.S.C., as amended, for persons in the Government service employed intermittently. Members who are officers or employees of the United States Government shall not receive compensation for service on the Council.

ANNUAL COST ESTIMATE

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is $98,842. The estimate of annual person-years of staff support required is 0.3, at an estimated annual cost of $46,027.

REPORTS

The Council may prepare, for inclusion in the Biennial Report prepared by the Director, NIH, under section 403 of the PHS Act, as amended (1) comments reflecting the activities of the Council in the fiscal years in which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The Council may prepare any additional reports as it may determine appropriate.

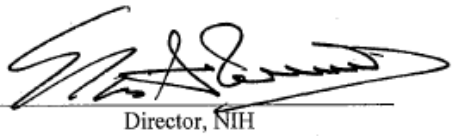
In the event a portion of a meeting is closed to the public, as determined by the Secretary of Health and Human Services, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report shall be prepared which shall contain, as a minimum, a list of members and their business addresses, the Council's functions, dates, and places of meetings, and a summary of Council activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the National Diabetes and Digestive and Kidney Diseases Advisory Council will expire on October 31, 2010.

APPROVED

9/2/07
Date



Director, NIH

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CHARTER FILING DATE 10/31/08

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

> ***The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.***

How do I get started?
You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:** https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement
4 Extension
5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution

8 Change of Institute or Division (noncompeting continuation)
9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR*, *NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you

are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available.

Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Teresa Lindquist, lindquit@niddk.nih.gov or 301-451-6418.

National Diabetes and Digestive and Kidney Diseases Advisory Council: Advisory Council Operating Procedures

February 2009
Expiration: February 2010

A. Purpose

This documents operating procedures established annually by the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) for use of council-delegated authorities. These authorities establish program management and council review procedures for the Institute's extramural programs and establish authorities for management actions undertaken by staff.

In general, the Council makes three types of recommendations relating to second level review of scientific review group (SRG) actions: (1) the Council can concur with the SRG critique; (2) it can suggest a different budget and/or a different length of the grant period; and (3) it can advise deferral of an application for re-review. Specific procedures are given below for each of these types of actions. These procedures are meant to ensure a level of uniformity and comparability across the Council's three subcommittees, which are aligned with the Institute's programmatic divisions. Those subcommittees of Council are free to develop and utilize their own procedures with the understanding that they be consistent with the operating procedures.

B. Background

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other National Institutes of Health (NIH) awarding Institutes are required by policy to establish procedures for interactions between Advisory Councils and the staff responsible for the day-to-day management of extramural portfolios. These procedures, referred to as Council-delegated authorities, govern staff and NDDKAC responsibilities with regard to grant portfolio management.

C. Definitions

1. ***Council Delegated Authorities***: Those actions negotiated between the NDDKAC and the Director, NIDDK that govern management of the Institute's extramural program portfolio.

2. ***En Bloc Action***: An action taken by Council on a group of applications under review rather than on specific individual applications being presented to NDDKAC for review.

3. ***Staff Actions*****:** Actions that, based on policy and procedures, do not require a specific action on the part of the NDDKAC but are simply reported for their information. These actions include, but may not necessarily be limited to: (a) change of grantee institution, (b) change of principal investigator, (c) administrative supplements, (d) staff restoration of funds for time and amount, (e) no-cost extensions, and (f) phase-out or interim support.

4. ***Communication Letter:*** A communication between an applicant and Institute staff that is included for NDDKAC information purposes. Communication letters may or may not be acted upon by Council and need not be brought up for special discussion.

D. Policy and Implementation Procedures

The NDDKAC by approval has delegated authority to the Director, NIDDK for staff to negotiate adjustments in dollars and/or the terms and conditions of grant and cooperative agreement awards recommended by the Council. In general, these operational guidelines for administrative actions are developed to provide a day-to-day framework for the smooth and effective operations necessary after review of grant applications by the Council. They are principally intended to enhance the administration of the federal assistance portfolio by the NIDDK.

NIDDK program and grants management staff analyze and review applications, i.e., noncompeting continuation applications and competing applications (new, renewal, or supplemental) before issuing a grant award. NIDDK staff negotiates appropriate adjustments, when applicable, for such changes as the base used for recovery of facilities and administrative costs and/or legislatively imposed salary or other limits. Also, staff can make adjustments to reconcile inconsistencies between SRG recommended budgets and approved activities.

Administrative requests for increases in direct costs, which are the result of marked expansion or significant change in scientific content after formal peer review, will be referred to the Council for advice and recommendation. The NIDDK Director will determine whether the urgency is sufficient to warrant interim consultation with the Council by mail, e-mail, facsimile or telephone, instead of delaying action until the next Council meeting, or by mutual agreement, the Chairpersons of the Advisory Council may act on behalf of the Council as a whole.

Actions not requiring NDDKAC review or advice are: (1) change of institution, (2) change of principal investigator, (3) phase-out or interim support, or (4) additional support either to meet the increased cost of maintaining the level of research previously recommended, or to accommodate activities or to meet needs judged by staff to be within the scope of the previously peer reviewed project. The Council will be provided with notice of general solicitations for administrative supplements if they apply to an entire class of applications.

In addition, NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided justification in a communication letter, and the restoration is in the best interest of the Institute and the project is of high programmatic relevance. Staff will record the action taken and its justification in a memo to the file. In addition, this will be summarized for Council information at the next regular scheduled meeting.

The National Institutes of Health (NIH), in an effort to improve the efficiency of making awards, authorized the use of an expedited review process by initiating OER Policy Announcement 1999-01 entitled "Council Operating Procedure for Expedited En Bloc Concurrence." NIDDK makes use of an expedited concurrence of en bloc actions to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive and responsible manner.

All grant and cooperative agreement applications, excluding those from foreign organizations, which have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), will follow a process of expedited concurrence whereby the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee shall consist of the Council Executive Secretary and six members of the NDDK Advisory Council. Two members will be selected from each subcommittee of the NDDK Advisory Council.

The Executive Secretary will alert the concurrence committee members with responsibility for expedited concurrence when review outcomes for eligible applications are available in the Electronic Council Book. The Electronic Council Book enables members to access: Application Number, Principal Investigator, Project Title and Percentile/Priority Score.

Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within seven days of notification of posting is required for expedited concurrence approval. Any member may bring an application to full NDDKAC consideration without the need for justification. Any single vote for non-concurrence within the allotted time period will result in that application going for regular consideration to the NDDKAC under its normal procedures for concurrence. Members not acting upon an application within the allotted time period after posting will be considered to have abstained from a vote on that application. Expedited listings lacking enough votes for final action will be presented to the regular NDDKAC meeting for review.

The full NDDKAC will be provided with a list of all applications eligible for expedited concurrence, as well as the outcome of the vote by the concurrence committee members on those applications. The Executive Secretary will report the expedited concurrence recommendations during the closed session of the full Advisory Council meeting when reviewed applications are discussed. The NDDKAC may reconsider the parameters for expedited eligibility at the first Council meeting of each calendar year.

The NDDKAC also advises the Institute on: The adequacy of the initial review process, including appeals to grant application review; nominations for and extensions of, Method to Extend Research in Time (MERIT) awards; and, funding of applications with Special Emphasis dollars.

Finally, the NDDKAC will receive a report annually on the activities of the NIDDK Board of Scientific Counselors.

E. Exceptional Situations

As circumstances require, based on programmatic considerations, the Director, NIDDK after consultation with Council, may make exceptions to these guidelines.

Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures across extramural divisions. Nonetheless, circumstances may require the deviation from the prescribed procedure in order to achieve the mission of the NIDDK. By NDDKAC delegated procedures, the Director, NIDDK has authority to act upon unusual or extenuating circumstances. These actions are usually discussed by a subset of Council members selected by the Director and Executive Secretary of NDDKAC. Any actions of this exceptional nature must be appropriately documented as necessary for the official record, and should be reported to Council at its next scheduled meeting.

F. References

1) Public Health Service Act as amended, 42 USC 52h, 42 USC 241, 42 USC 284a
2) NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management (http://www1.od.nih.gov/oma/manualchapters/management/1805/)
3) NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for NIH Special Government Employee SGE Advisory Committee Members (http://www1.od.nih.gov/oma/manualchapters/management/1810-1/)
4) NIH Manual Chapter 3005, Review and Evaluation of Intramural Programs (http://www1.od.nih.gov/oma/manualchapters/intramural/3005/)
5) NIH Manual Chapter 4204-204B, Peer Review Process

6) NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organizations
7) NIH Manual Chapter 54107, Review of Applications and Award of Grants Involving Human Subjects
8) NIH Manual Chapter 54206, Responsibility for Care and Use of Animals
9) NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities
10) OER Policy Announcement 1999-01 – Council Operating Procedure for Expedited En Bloc Concurrence
11) OER Policy & Guidance: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page (http://grants.nih.gov/grants/funding/women_min/women_min.htm)
12) OER Policy & Guidance: Inclusion of Children Policy Implementation (http://grants.nih.gov/grants/funding/children/children.htm)

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(All terms end October 31 of year in parentheses)
(Subcommittee membership also shown in parentheses after name)

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Advisory Council Meetings Dates: 2009 - 2011

2009
February 18 (Wednesday)
May 13 (Wednesday)
September 9 (Wednesday)

2010
February 24-25 (Wednesday and Thursday)
May 12-13 (Wednesday and Thursday)
September 22-23 (Wednesday and Thursday)

2011
February 16-17 (Wednesday and Thursday)
May 11-12 (Wednesday and Thursday)
September 7-8 (Wednesday and Thursday)

All meetings will be held in Building 31C, Rooms 10, 6, and 7.

Sample NDDKDAC Agenda

179th Meeting of the
NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

Building 31, C Wing, 6th Floor, Conference Room 10

February 18th 2009

OPEN SESSION 8:30 a.m. to 11.45 a.m.

I.	**CALL TO ORDER**	**Dr. Rodgers**
II.	**CONSIDERATION OF SUMMARY MINUTES OF THE 178th COUNCIL MEETING**	**Dr. Rodgers**
III.	**FUTURE COUNCIL DATES**	**Dr. Rodgers**

2009
May 13, 2009
September 9, 2009

2010
February 24-25, 2010
May 12-13, 2010
Septem ber 22-23, 2010

2011
February 16-17, 2011
May 11-12, 2011
Septem ber 7-8, 2011

IV.	**ANNOUNCEMENTS**	
	Confidentiality/Conflict of Interest	**Dr. Stanfield**
V.	**NIH PEER REVIEW UPDATE**	**Dr. Willard**
VI.	**REPORT FROM THE NIDDK DIRECTOR**	**Dr. Rodgers**
VII.	**COFFEE BREAK 10:15 a.m.**	

VIII. ADVISORY COUNCIL FORUM **Dr. Margolis**
- Supporting Collaborative Research

IX. SCIENTIFIC PRESENTATION **Dr. Mitch**
- Muscle Wasting in Catabolic Diseases

X. ADJOURN FOR LUNCH 11:40 a.m.

XI. SUBCOMMITTEE MEETINGS

1:00 to 4:00 p.m.

Diabetes, Endocrinology, and Metabolic Diseases
Building 31 C Wing, 6th Floor, Conference Room 10

Open Session: 1:00 p.m. – 2:30 p.m.
Closed Session: 2:30 p.m. – 4:00 p.m.

Digestive Diseases and Nutrition
Building 31 C Wing, 6th Floor, Conference Room 6

Open Session: 1:00 p.m. – 2:30 p.m.
Closed Session: 2:30 p.m. – 4:00 p.m.

Kidney, Urologic, and Hematologic Diseases
Building 31 C Wing, 6th Floor, Conference Room 7

Open Session: 1:00 p.m. – 2:30 p.m.
Closed Session: 2:30 p.m. – 4:00 p.m.

CLOSED SESSION 4:10 p.m. to 4:40 p.m.

XII. REPORTS OF SUBCOMMITTEES: **Dr. Stanfield**
CONSIDERATION OF APPLICATIONS

Diabetes, Endocrinology, and Metabolic Diseases
Digestive Diseases and Nutrition
Kidney, Urologic, and Hematologic Diseases

XIII. Report from the Intramural Acting Scientific Director **Dr. Levin**

XIV. ADJOURNMENT **Dr. Rodgers**

Sample of NDDKDAC Meeting Minutes

Meeting Minutes
Department of Health and Human Services
National Institutes of Health
National Diabetes and Digestive and Kidney Diseases Advisory Council
May 23, 2008

I. CALL TO ORDER

Dr. Griffin P. Rodgers, Director

Dr. Griffin P. Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 177th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m., Friday, May 23, 2008, in Conference Room E1/E2, Natcher Building (45), NIH, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Nancy Andrews
Dr. Janice Arnold
Ms. Janet Brown
Dr. Charles Elson
Dr. James Freston
Dr. Mark Magnuson
Dr. Juanita Merchant
Dr. William Mitch
Dr. Brian Monahan
Dr. Jerry Palmer
Dr. David Perlmutter
Ms. Margery Perry
Ms. Lisa Richardson
Dr. Anthony Schaeffer
Mr. James Schlicht
Dr. Patrick Tso

Also present:
Dr. Griffin P. Rodgers, Director, NIDDK, and Chairperson, NIDDK Advisory Council
Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

B. NIDDK STAFF AND GUESTS

In addition to Council members, others in attendance included NIDDK staff members, Center for Scientific Review (CSR) Scientific Review Officers, and other NIH staff members. Guests were present during the open sessions of the meeting. Attendees included the following:

Abraham, Kristin- NIDDK
Agodoa, Lawrence – NIDDK
Akolkar, Beena – NIDDK
Appel, Michael – NIDDK
Arreaza-Rubin, Guillermo – NIDDK
Amir, Syed – CSR
Barnard, Michele – NIDDK
Bethum, Najma – CSR
Beverly, Kevin - Social Scientific Systems
Bishop, Terry –NIDDK
Blondel, Oliver – NIDDK
Brown, Clarice - Social Scientific Systems
Calvo, Francisco – NIDDK
Carrington, Jill – NIDDK
Castle, Arthur – NIDDK
Chang, Debuene – NIDDK
Christiansen, Dane - Digestive Diseases National Coalition
Clay, Shawna – NIDDK
Cowie, Catherine – NIDDK
Curtis, Leslie – NIDDK
Davila-Bloom, Maria – NIDDK
Densmore, Christine – NIDDK
Doo, Edward – NIDDK
Doherty, Dee – NIDDK

Donohue, Patrick – NIDDK
Edwards, Michael – NIDDK
Eggerman, Thomas - NIDDK
Eggers, Paul - NIDDK
Everhart, James - NIDDK
Farishian, Richard - NIDDK
Faupel-Badger – NIDDK
Ferguson. Frances - NIDDK
Feld, Carol - Hill Group
Fisher, Rachel - NIDDK
Fonville, Olaf - NIDDK
Gansheroff, Lisa - NIDDK
Garfield, Sanford - NIDDK
Giambarresi, Leo - American Urological Foundation
Goter-Robinson, Carol – NIDDK
Greene, Elizabeth – NIDDK
Gutierrez-Lugo, Elizabeth – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hanlon, Mary – NIDDK
Harris, Mary – NIDDK
Hilliard, Trude – NIDDK
Hoff, Eleanor – NIDDK
Hoofnagle, Jay – NIDDK
Horlick, Mary – NIDDK
Hoshiazi, Deborah – NIDDK
Howard, Stuart – NIDDK
Hubbard, Van – NIDDK
Hyde, James – NIDDK
James, Stephen – NIDDK
Jerkins, Ann – CSR
Johnson, Michelle – NIDDK
Jones-Perry, Aretina – NIDDK
Jones, Teresa – NIDDK
Jordan, Craig – NIDCD
Karp, Robert – NIDDK
Ketchum, Christian – NIDDK
Kim, Sooja - CSR
Kimmel, Paul - NIDDK
Kusek, John - NIDDK
Laughlin, Maren - NIDDK
Lee-Chon, Angie - NIDDK
Leschek, Ellen - NIDDK
Linder, Barbara - NIDDK
Malik, Karl - NIDDK
Manouelian, Denise - NIDDK
May, Michael (Ken) - NIDDK
McGowan, Melissa - NIDDK
McKeon, Catherine - NIDDK
Miles, Carolyn - NIDDK
Miller, David - NIDDK
Miller, Megan - NIDDK
Moen, Laura - NIDDK
Mims-Moxey, Marva - NIDDK
Mullins, Christopher - NIDDK
Narva, Andrew -NIDDK
Nicholson, Krystle- NIDDK
Newman, Eileen -NIDDK
Nyberg, Leroy - NIDDK
Patel, D.G. - NIDDK
Payne, Phyllis - NIDDK
Pike, Robert - NIDDK
Podskalny, Judith - NIDDK
Pope, Sharon - NIDDK
Rasooly, Rebekah - NIDDK
Robinson, Terra -NIDDK
Rosenberg, Mary Kay- NIDDK
Ross, Catherine – Bio Search Team Placement
Rushing, Paul - NIDDK
Sahai, Atul - NIDDK
Salomon, Karen - NIDDK
Sankaran, Lakshmanan - NIDDK
Sato, Sheryl - NIDDK
Savage, Peter - NIDDK
Sechi, Salvatore - NIDDK
Seef, Leonard - NIDDK
Sharpe, Angie – Consortium of Social Science Associations
Sheard, Nancy - CSR
Singer, Elizabeth - NIDDK
Shoneck, Ted – Tunnell Government Services Group
Smith, Philip - NIDDK
Star, Robert - NIDDK
Stone, Arthur - NIDDK
Tatham, Thomas - NIDDK
Torrance, Rebecca – NIDDK
Wade, Kristen - NIDDK
Wallace, Julie - NIDDK
Wellner, Robert - NIDDK
Weisman, Jennifer - NIDDK
Wilder, Betsy - NIDDK
Wilson, Teresa - NIDDK
Williams, Garman - NIDDK
Wright, Elizabeth -NIDDK
Wright, Daniel - NIDDK
Woynarowska, Barbara – NIDDK
Xie, Yining -NIDDK
Yanovski, Susan - NIDDK
Zeller, Charles - NIDDK

C. ANNOUNCEMENTS
Dr. Griffin P. Rodgers, Director, NIDDK

Dr. Rodgers thanked all the Council members for their participation and made the following announcements.

Council Members

Dr. David Altshuler: Attending his first meeting as a new Council member, Dr. Altshuler is Professor of Genetics and Medicine at Harvard Medical School and Director of the Program in Medical and Population Genetics at the Broad Institute of Harvard and the Massachusetts Institute of Technology. His research focuses on two intertwined goals: (1) to characterize and catalogue patterns of human genetic variation, and (2) to apply this information to dissect the genetic contribution to common human diseases, in particular type 2 diabetes and cardiovascular disease risk factors. For example, Dr. Altshuler is pursuing an exciting new project in premature coronary artery disease. His research interests also include prostate cancer, systemic lupus erythematosus, rheumatoid arthritis, and age-related macular degeneration. Throughout his career, Dr. Altshuler has contributed to knowledge of the patterns of genetic variation in the human genome; led in the creation of publicly available, genome-wide single nucleotide polymorphism (SNP) and haplotype maps; developed methods for genetic analysis; and contributed to the discovery of genes for type 2 diabetes, systemic lupus erythematosus, and prostate cancer. Dr. Altshuler earned both his M.D. and Ph.D. degrees from Harvard in 1994. His research has been funded by the NIDDK and other NIH institutes since 2002. He is presently Principal Investigator on three NIH supported research projects and is also Co-Investigator of a Center for High Throughput SNP Genotyping and Analysis funded by the National Center for Research Resources (NCRR).

NIDDK Grantees

Dr. Sum P. Lee: A long-standing NIDDK grantee and former member of the NIDDK Advisory Council, Dr. Lee has accepted the position of Dean of the Faculty of Medicine at the University of Hong Kong. Dr. Lee is a distinguished gastroenterologist and Professor of Medicine in the Department of Medicine at the University of Washington. Part of Dr. Lee's recent research focus has been on the relationship between obesity, insulin resistance, and the metabolic syndrome in pregnancy. This research also includes study of intrauterine programming of the developing fetus, and subsequent evolution of growth, development, diabetes, and obesity. Dr. Lee has been supported in his research by grants from NIDDK since 1992. He presently holds three grants from the NIDDK and one from the National Cancer Institute. Dr. Lee served as a member of the NIDDK Advisory Council from 2002 to 2005. The NIDDK wishes him well in his new position.

NIDDK Staff Members

Division of Kidney, Urologic and Hematologic Diseases--Dr. Paul Kimmel: In March, Dr. Kimmel rejoined the Division as Director of the Translational Kidney Genetics Program and a full-time Program Officer for the Clinical Acute Kidney Injury Program. Dr. Kimmel will also be spending some time at The George Washington University as a Professor of Medicine and will continue to be involved in clinical and research activities. Previously, Dr. Kimmel was the Director of the Division of Renal Diseases and Hypertension at George Washington University, and the Director of Education of the American Society of Nephrology. His clinical interests include diabetic nephropathy, cytokine biology in chronic kidney disease, psychological adaptation to chronic kidney disease, and HIV-associated renal diseases. A graduate of Yale University, Dr. Kimmel received his M.D. from New York University, and trained at Bellevue Hospital and the Hospital of the University of Pennsylvania. From 1998 to 2001, he served as a Program Director at the NIDDK with responsibility for overseeing

the Diabetic Nephropathy Program and HIV Kidney Disease Program, as well as serving as the Project Scientist for the Family Investigation of Nephropathy and Diabetes (FIND).

Division of Diabetes, Endocrinology and Metabolism—Dr. Peter Savage: The Division is pleased to have Dr. Savage join their efforts as a Special Advisor on Clinical Research on detail from the National Heart, Lung, and Blood Institute (NHLBI). Dr. Savage received his M.D. from Tufts Medical School and completed post-doctoral training in internal medicine and a fellowship at Yale University prior to joining the NIDDK Intramural Program in Phoenix, AZ. He has served as an Assistant Professor of Medicine and as Deputy Director of the Adult Care Unit at the Diabetes Research and Training Center, University of Michigan; as Chief of the Endocrinology/Hypertension Section of the Detroit VA Hospital; and as an Associate Professor of Medicine at Wayne State University. At the NHLBI, he served as Chief, and later Director, of the Clinical and Genetic Epidemiology Branch within the Division of Epidemiology and Clinical Applications. Dr. Savage has had a leadership role for a large number of epidemiology studies, clinical trials, and biostatistical programs. While at the NHLBI, he played a major role in expanding clinical research on the cardiovascular complications of diabetes and was a key person involved in the planning and development of the ACCORD clinical trial. He also served for ten years as the NHLBI's representative on the statutory Diabetes Interagency Coordinating Committee.

Review Branch--Dr. Thomas Tatham: In March, the NIDDK's Review Branch welcomed Dr. Tatham as a new Scientific Review Officer. Dr. Tatham earned a Ph.D. in Experimental Psychology from Temple University in animal learning. He subsequently received post-doctoral training in psychopharmacology. He is also a graduate of the Commerce Department's Science and Technology Fellowship Program. His academic career includes serving on the faculties of Mount Union College and the Uniformed Services University of the Health Sciences. Dr. Tatham came to the NIH in 1999 and has served as a Scientific Review Officer at the NIH Center for Scientific Review (CSR). In addition to his regular duties, Dr. Tatham served for several years as the CSR's Information Technology Liaison and, more recently, as Associate Director for Knowledge Management. In these capacities, he streamlined procedures for shipping materials to reviewers; produced a series of programs that automate many of the administrative aspects of summary statement production; and led an effort to use textmining technology to automate the referral of grant applications. His accomplishments have been recognized by a DHHS Secretary's Award, Directors' Awards from both the NIH and the CSR, and the CSR Explorer Award.

Grants Management Branch: Three new Grants Management Specialists have joined the Branch: Ms. Krystle Nicholson, Ms. Marilyn Rosendorf, and Ms. Leslie Whipp.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 176th COUNCIL MEETING

Following a motion, the Council approved the Summary Minutes of the 176th Council meeting by voice vote.

III. FUTURE COUNCIL DATES

Dr. Rodgers called the attention of the Council to future meeting dates:

2008
September 24 (Wednesday)

2009
February 18-19 (Wednesday and Thursday)
May 13-14 (Wednesday and Thursday)
September 9-10 (Wednesday and Thursday)

Most of these meetings in 2009 are expected to be on a single day—Wednesday. However, the NIDDK requests that Council members hold both Wednesday and Thursday to ensure flexibility should a situation arise where a longer meeting is required.

IV. ANNOUNCEMENTS

Dr. Brent Stanfield
Director of Extramural Research, NIDDK

Confidentiality

Council members were reminded that material furnished for review purposes and discussion during the closed portion of the meeting is considered privileged information. The outcome of such discussion during the closed session may be disclosed only by the staff and only under appropriate circumstances. All communication from investigators to Council members regarding actions on applications must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict of Interest

Advisors and consultants serving as members of public advisory committees may not participate in situations in which any violation of conflict of interest laws and regulations may occur. Responsible NIDDK staff shall ensure that a committee member does not participate in, and is not present, during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or organization with which the member is connected. To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Dr Stanfield asked each Council member to read the statement provided regarding conflict of interest, and to sign and return it to him.

At Council meetings when applications are reviewed in groups without discussion, i.e., "en bloc" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict. With respect to multi-campus institutions of higher education, Dr. Stanfield noted that an employee may participate in any particular matter affecting one campus of a State multi-campus institution of higher education, if the employee's disqualifying financial interest is employment in a position with no multicampus responsibilities at a separate campus of the same multi-campus institution.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Griffin P. Rodgers

Fiscal Year 2009 Appropriations Bill

Dr. Rodgers noted that the President's budget request for the NIDDK for Fiscal Year 2009 is approximately $1.708 billion, which represents about a 0.1 percent increase over the Fiscal Year 2008 appropriation. Most of the Institutes and Centers at the NIH have a similar percentage increase. With this budgetary landscape NIDDK will need to manage its resources with great care, and to shepherd the funds that become available when ongoing projects are terminated so that support can be provided to the most scientifically promising new research. This task is made more difficult because of a biomedical inflation rate of about 3.5 percent, which has led to a decline in the purchasing power of investigators over the last several years.

Congressional Interactions

The NIH Director, Dr. Elias Zerhouni, testified on the Fiscal Year 2009 President's budget request for NIH at a single House hearing, along with witnesses from the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Agency for Healthcare Research and Quality (AHRQ). Given the Department-wide scope of this hearing, NIH Institute and Center Directors did not participate. Although a Senate hearing for the NIH was planned, it was later cancelled.

The Fiscal Year 2009 appropriations process has been much more streamlined than the Fiscal Year 2008 cycle, during which there were several NIH theme hearings. However, following Dr. Zerhouni's testimony, the NIH was visited by Congressman David Obey, the Chairman of the full House Appropriations Committee, as well as the Chairman of the Subcommittee with jurisdiction over the NIH--along with several other committee members. This visit provided the NIH with an additional opportunity to highlight recent accomplishments. Formal presentations were made by Dr. Francis Collins, Director, National Human Genome Research Institute (NHGRI); Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID); Dr. Betsy Nabel, Director, National Heart, Lung, and Blood Institute (NHLBI); and others. Presentations focused on several topics including: recent genetic discoveries linked to a wide range of diseases-- including some strongly linked to kidney cancer; new surgical techniques for minimally invasive therapies; and new diagnostic techniques for heart attacks and strokes. Dr. Rodgers joined with a few other Institute Directors who gave brief remarks and met with the Members and their staff during their visit to the NIH Clinical Center.

Dr. Rodgers noted that as a newly appointed Institute Director he has taken the opportunity to make several introductory visits to Members of appropriations and authorizing committees that have the NIH within their jurisdiction. He has visited close to three dozen House and Senate Members, and additional visits are scheduled. During these visits, the Members have generally shown a great interest in learning more about both the NIDDK and the NIH. They have been receptive to Dr. Rodgers' message that research plays an essential role in the public health and in the economic health of the Nation. About 20 percent of these visits have led to an invitation to Dr. Rodgers to join the Members locally in their communities to speak further about areas of interest to their constituents.

Paylines

For Fiscal Year 2008, the NIDDK has been able to achieve the goal of raising its R01 payline from 13 percent to 17 percent for all applicants, and from 15 to 19 percent for new investigators. As reported at the last Council meeting, several factors have enabled these payline increases.

Numbers of New Investigators

New R01 investigators continue to be an NIH-wide priority, with Institute-specific goals set for their support. The NIDDK goal is 166 for Fiscal Year 2008, which is slightly fewer than last year's goal of 188. These goals include individuals who will be funded within the general payline, as well as some individuals who score beyond that payline. Dr. Rodgers thanked the Council and the NIDDK staff for helping to identify the individuals to receive this funding.

Bridge Awards

The NIH Director's Bridge Award Program is continuing for a second year. This Program provides for one-year funding through an R56 grant for established investigators whose peer-review score on a competing application was near, but not quite within, the fundable range, and whose other means of

support were considered insufficient to enable them to continue their efforts until they could re-compete for an R01 grant. The continuity of funding provided by a Bridge Award permits the Principal Investigator additional time to strengthen an application for resubmission. Each Institute and Center is permitted to nominate eligible and worthy candidates for a first round of funding decisions. The NIDDK has been notably successful in participating in this Program.

Special Statutory Funding Program for Type 1 Diabetes Research

The Congress has extended funding for this Program for one additional year—through Fiscal Year 2009. Because this Program was approaching the end of its statutory funding envelope, the NIDDK previously requested and received permission to use multiyear funding authority to establish a new Type 1 Diabetes Pathfinder Award. This award was established to support exceptionally creative new investigators who propose innovative research projects that have the potential for unusually high impact in type 1 diabetes and its complications. It also complements ongoing NIH efforts to fund new investigators. Based on the large numbers of applications submitted, the Type 1 Diabetes Pathfinder Award has been well-received by the community. The NIDDK plans to make eight awards each of which may total up to $1.5 million in direct costs over a five-year budget/project period.

With the recent extension of the Special Statutory Program, the NIDDK is seeking to apply a multiyear funding approach again—this time for other new efforts that will not be limited to new investigators. The aim is to encourage groups of investigators to apply jointly for complex projects related to the complications of diabetes and to the genetics of type 1 diabetes. These research solicitations will be announced shortly, with the designation of "DP3" awards. Given that there is no guarantee of further Program extensions, multiyear funding approaches provide the NIH with the greatest flexibility for managing this Special Statutory Program. At the same time, Dr. Judith Fradkin, the Director of the NIDDK's Division of Diabetes, Endocrinology and Metabolic Diseases, arranged for an extensive external review of the clinical research studies that are already under way so that priorities can be established for either a possible Program close-out, or alternatively, a further funding extension, should that be provided by the Congress. On April 29 and 30, 2008, the NIDDK convened thirteen scientific leaders whose collective expertise encompassed clinical trial design, epidemiology, biostatistics, transplantation, genetics and immunity. They rendered a thoughtful analysis of nine large, multi-site clinical studies that are currently under way. A similar review is planned to analyze the basic research component of the Program, as well as activities focused on the development and use of animal models. The observations and recommendations from these processes will be of great assistance in the NIDDK's continuing management of this Program, which is vested in the Secretary of Health and Human Services and involves multiple NIH components and the CDC.

Funding Prospects for Scored vs. Unscored Applications Upon Resubmission

Dr. Rodgers presented a slide in follow-up to a question posed by a Council member at the last meeting regarding the percentage of unscored (streamlined) initial applications (A0 applications) that are eventually funded through a resubmission process. For both the NIH and the NIDDK, the slide presented 1996-2006 data in a line graph showing the percentage of both scored and unscored grant resubmissions (A1 and A2 applications) that were eventually funded (as a percentage of submitted A1 applications).

Dr. Rodgers noted the similarity of the NIH and NIDDK data, which is not surprising given that the NIDDK is the fifth largest NIH component and thus can have a large effect on NIH summary data. NIDDK-assigned grants represent about ten percent of all the grants processed by the NIH Center for Scientific Review, and are considered in well over 60 percent of the NIH Study Sections.

Although there is some yearly variation in the data, the overall picture is relatively stable. Of the NIDDK-assigned initial applications (A0) that are scored, roughly 55 percent are eventually funded through the resubmission and re-review process. This funding profile closely matches that of the NIH proper for scored applications. Of the NIDDK-assigned initial applications (A0) that are considered streamlined or unscored, only about 15-20 percent have received eventual funding—again closely matching the NIH data. The most recent, reliable data for the NIDDK unscored applications show that 15 percent receive eventual funding. The take-home message is that applications that receive scores upon initial submission have a much greater probability of eventual funding than those that are unscored.

VI. UPDATE: ACCORD Trial (ACTION TO CONTROL CARDIOVASCULAR RISK IN DIABETES TRIAL)

Dr. Peter Savage, Special Advisor on Clinical Research Division of Diabetes, Endocrinology and Metabolic Diseases

In introducing Dr. Savage, Dr. Rodgers noted that the NIDDK has been one of several co-sponsors of the ACCORD trial. Led by the NHLBI, this large trial is being conducted in a group of adults with established type 2 diabetes who are at especially high risk for cardiovascular disease. The NHLBI stopped one of the treatment arms in this trial--the intensive glycemic control (glucose-lowering) arm--18 months earlier than planned due to safety concerns that were raised following the review of available data. (Note: Information about the ACCORD trial can be found at: www.accordtrial.org/ *This website includes material published subsequent to the NIDDK Council meeting, i.e., the June 2008 article on ACCORD findings in the New England Journal of Medicine, as well as the June 2008 NHLBI Press Release.)*

Dr. Savage began by describing the complexity of the ACCORD trial, which has been a trans-NIH effort in many respects. In addition to receiving support from the NHLBI and the NIDDK, the trial is also supported by the National Institute on Aging (NIA), National Eye Institute (NEI), and the Centers for Disease Control.

ACCORD Trial Design

The ACCORD study is a multicenter, randomized clinical trial with a double-factorial design. The trial is conducted at 77 different sites around the country. The design of the trial included:

- Recruitment of over ten thousand patients with established type 2 diabetes, high glucose levels, and a high risk for cardiovascular disease events. The patients either had clinical cardiovascular disease (CVD) or they had at least two other CVD risk-factor abnormalities in addition to their diabetes.
- Testing of three separate treatment strategies to reduce cardiovascular disease: glycemic control, blood pressure control, and blood lipid control--according to specified targets.
- All interventions were with drugs approved by the FDA and on the market in the United States.
- Dr. Savage underscored that the primary focus of the trial is on the three treatment strategies and not on specific drug interventions. He described the strategies in general terms.
- For the glycemic control strategy, two targets were used for hemoglobin A1c (A1c) levels, which reflect an individual's average blood glucose level over the past three months. The targets were an intensive-control target of less than 6 vs. a standard-control target in the 7-7.9 percent range.
- For the blood pressure control strategy, a target systolic blood pressure of less than 120 millimeters of mercury was contrasted with a standard control of less than 140 millimeters of mercury. Physicians titrated the treatment to goal using a range of antihypertensive agents provided by ACCORD.

- For the lipid control strategy, all patients received statin therapy to reduce low density lipoprotein cholesterol (LDL-C) levels to less than 100 milligrams per deciliter. However, one group of patients also received fibrates to test their effects in increasing high-density lipoprotein cholesterol (HDL-C) levels and in lowering triglyceride (TG) levels.

The trial design included the participation of all patients in the glycemic-control strategy. Half of them were randomized to the intensive control group and half were randomized to the standard control group. To participate in the study, patients needed to be eligible for either a blood pressure or lipid intervention and they were randomized to those strategies within the two large glycemic control strategy groups.

The primary outcome in the ACCORD design is a composite CVD outcome of non-fatal myocardial infarction, non-fatal stroke, and CVD deaths. Cases are adjudicated by a committee blinded to the assignment of the patients. Comparisons are between the marginal results in each of the arms of the trial. Direct comparisons are not possible between the blood pressure control and lipid control groups because they were not randomized to permit that type of analysis. The statistical power of the ACCORD design is about 89 percent power to detect a 15 percent effect for glycemic control; about 94 percent power to detect a 20 percent effect for blood pressure control; and about 87 percent power to detect a 20 percent effect for lipid control.

ACCORD Trial Monitoring

The monitoring of the trial has been extensive, particularly the oversight provided by an independent Data and Safety Monitoring Board (DSMB). A requirement for starting the trial was to test a vanguard of 1,000 patients for a year in order to assess safety, as well as the ability to achieve or come close to the treatment goals and to maintain separations among the groups. Several indicators were analyzed in the glycemic control strategy in addition to A1c levels. For example, one concern was whether these generally older patients (average age of 62 years) with significant co-morbidities were at risk for hypoglycemia. An external working group was established to review not only the frequency of hypoglycemia, but also the way the study responded to it. Other indicators that were monitored included the rate of hospitalized heart failure, heart failure symptoms, weight gain, and ALT levels. The trial design included following a whole series of adverse events, and the efficacy of the primary outcome. Several substudies also are underway. One of the objectives was to determine whether or not intensive glucose control is associated with improvement or deterioration in mental function, another was to assess diabetic retinopathy, a third was an economic substudy.

Termination of Intensive Glycemic Control Component of ACCORD Trial

In February 2008, the NHLBI announced that it was terminating the intensive glycemic control component of the trial based on the recommendation of the independent Data and Safety Monitoring Board (DSMB). (See NHLBI press release at: http://public.nhlbi.nih.gov/newsroom/home/GetPressRelease.aspx?id=2551)

For several months, the DSMB closely watched a slowly developing trend in excess deaths in the intensive glycemic vs. the standard treatment glycemic intervention groups. After careful monitoring, review of additional data analyses, and deliberation, the DSMB recommended to the NHLBI Director that this part of the study be stopped because of concern for the participants' safety. A discussion then occurred as to whether the entire trial should be halted. Because of interest in the questions addressed in the other arms of the trial, the NHLBI determined that the best course of action was to continue the study, but to place all participants on the standard glycemia control group and follow them all to the scheduled conclusion of the study in 2009, with final results expected to be reported in 2010.

The excess deaths in the intensive glycemic control arm occurred despite a nonsignificant reduction in that group of overall cardiovascular events as compared with the standard glycemic control group.

Nevertheless, the DSMB concluded that any significant or major excess in deaths would counteract whatever other benefits were being seen in the intensive glycemic control arm of the trial. It should be noted that the death rates were lower in ACCORD than previously reported in most type 2 diabetes studies of comparable subjects--although it is difficult to make comparisons of ACCORD data with published data from other studies. The ACCORD patients tended to have better control of their glucose levels, better blood pressure levels, and better lipid levels than most patients in earlier studies.

Implications of ACCORD Trial Results for Diabetes Care

The excess deaths in the intensive glycemic control group appeared to be mainly cardiovascular, but the specific cause(s) has not been identified, despite extensive efforts on the part of the ACCORD Data Coordinating Center. Because the main design of ACCORD focuses on strategies for controlling glycemia, blood pressure and lipid levels, rather than on specific drug interventions, it is difficult to pinpoint the cause(s) of the excess deaths. Had the trial design been focused on assessing specific medical interventions, it would probably have been criticized for not reflecting the way that patients with diabetes are treated with multiple drugs in medical practice. Patients in ACCORD took several drugs because of their multiple risk factors and combinations of risk factors that were being addressed. To date, there has been no clear indication that rosiglitazone or any of the other medications used in the ACCORD trial are related to the excess deaths observed; however, the search for causes is continuing.

Several questions are raised by the finding that the overall CVD rate was lower (but not significantly lower) in the intensive glycemic control group, yet there was an excess of cardiovascular mortality. Is there something about the underlying cardiovascular disease in these patients? Is there something about the diabetes itself? Is a combination of factors responsible? While these questions are difficult, they are very important because the answers could illuminate whether there is a subset of patients for whom intensive glycemic control carries a risk for CVD death. If these patients could be identified, glycemic targets could be tailored to account for the specific risk of this subgroup, whereas many other diabetes patients without such risk might be able to benefit from more intensive glycemic control. Although there is unequivocal evidence that more intensive glycemic control is beneficial in terms of the microvascular complications of type 2 diabetes, the hoped-for positive effect of this strategy on CVD rates has not been realized. Moreover, the question may be more complex than previously thought, because a serious question now exists as to whether or not there may be subsets of type 2 diabetes patients in terms of CVD risk.

An overriding treatment question is: For what types of patients do the results of the ACCORD trial have relevance or applicability? The results apply most directly to patients who are similar to the ACCORD patient population. The ACCORD patients have type 2 diabetes and existing CVD, or they are at high risk of developing CVD because they have multiple CVD risk factors in addition to their diabetes. The ages of ACCORD participants at entry to the study ranged from around 40 to around 80 years, with an average age of 62 years. The average duration of their diabetes at entry to the study was 10 years, and, in general, they had been treated with some type of drug therapy before joining the study.

With respect to A1c levels, the ACCORD participants attained a median of 6.4 percent in the intensive glycemic control group and around 7.5 percent in the standard glycemic control group. At the present time, it is not believed that the findings of the ACCORD trial would invalidate the A1c guidelines of the American Diabetes Association (ADA), which continues to advise people with diabetes to strive for an A1c level of less than 7 percent. (Note: The following is a link to the ADA

statement related to the ACCORD trial: http://www.diabetes.org/for-media/pr-ada-statement-related-to-accord-trailannouncement- 020608.jsp. However, the ACCORD findings do raise a question about how widely applicable intensive therapy should be. When all the ACCORD data are available and published (with the first publication expected in June 2008), there may be a need to revisit the current guidelines and consider whether modifications may be necessary. Importantly, guidelines about A1c levels currently have a statement underscoring the need to individualize therapy in diabetes patients and this requires greater emphasis. However, the ACCORD patients were relatively indistinguishable from other type 2 diabetes patients with CVD or at high risk of developing CVD.

It is possible that the ACCORD findings of excess deaths associated with intensive glycemic control may not apply to type 2 patients who do not share the characteristics of the ACCORD participants, for example, those with recent-onset diabetes and/or low CVD risk. However, the study wasn't designed in a way to answer that question. One can look at other studies, such as the United Kingdom Prospective Diabetes Study (UKPDS), in which there was no excess mortality in the intensive glycemic control group in type 2 diabetes patients who were in the early stages of diabetes. However, in making comparative analyses, one must consider differences between the ACCORD trial and other studies with regard to the level of treatment and the degree to which glucose was controlled. Light may be shed on these issues by other ongoing trials, along with discussions at the American Diabetes Association meeting in June, 2008.

The ACCORD findings reinforce the importance of randomized controlled clinical trials to determine the optimal treatment for patients with diabetes and other chronic diseases. They also illustrate a need for better systems to monitor the effects of drug interventions. In many cases, these interventions have become very complex because of the multiple risk factors in patients with long-standing chronic diseases such as type 2 diabetes. *(Note: Dr. Savage recognized the contributions of Dr. Denise Simmons-Morton, the Project Officer for the ACCORD trial, who was unable to attend the Council meeting.)*

Council Questions and Discussion

What proportion of the patients in the intensive glycemic control group actually reached a target of 6 or lower on their A1c levels? While he could not provide the exact percentage, Dr. Savage responded that there were some patients whose A1c levels were in the 5's. In general, the A1c levels came down to the 6.4 range at the end of the first year and then remained essentially flat after that. However, there was a spectrum of A1c levels that ranged from normal into the mid 7's--with most patients clustered around the median.

Were there more cardiovascular events at the really low A1c levels? Dr. Savage noted that there were some details of the study that he couldn't provide prior to publication of the main results of the glycemic intervention. However, there was no evidence that attaining a lower A1c level, in and of itself, was a risk factor. On the other hand, patients whose type 2 diabetes was of shorter duration found it easier to lower their A1c levels. Epidemiologic studies may be performed on the all the data when they are published; however, the trial wasn't designed to answer the question posed by the Council in the intensive glycemic control group.

Could you elaborate on whether there has been some movement to A1c guidelines that are lower than the ADA guidelines? Dr. Savage responded that there is a European guideline of 6.5 percent and that the Association of Clinical Endocrinologists in the U.S. has recommended 6.5 percent. As continuous glucose monitoring and feedback devices are developed further, it may be appropriate to look at guidelines again, because more intensive glycemic control with less variation in glucose levels than is currently possible may provide a benefit to some patients. Researchers would be in a better position to know the answer if they had the technology to replicate with precision the normal metabolic control

of glucose and to avoid excursions in patients that inevitably occur when administering drugs whose effects may be delayed by several hours. For now, however, treatment approaches depend on the drug regimens available and on consideration of the results obtained from large, multisite research efforts such as the ACCORD trial and other studies.

Has the ACCORD trial raised questions in the public's mind more broadly? For example, is it possible that diabetes patients might not take medications to get their A1c levels into the 7's because of concerns they have about the excess CVD deaths in ACCORD, even though these excess deaths were only seen in the intensive glycemic control group for which the A1c target was 6.4? Also, might patients ease off on efforts to control their blood pressure and lipid levels—even though those components of the ACCORD trial did not involve excess deaths as seen in the intensive glycemic control group? Among type 2 diabetes patients who might meet the standards of this trial in America, is it known what fraction is anywhere near the 7.5 A1c target level of the standard glycemic control group in ACCORD?

Dr. Savage responded that one of the studies that will emerge from the ACCORD trial will look at data from the National Center for Health Statistics to try to determine whether A1c levels are coming down among diabetes patients in America. The CDC has reported that levels have dropped recently. However, the average A1c level in the overall U.S. diabetes population is still in the high 7 percent range, so there is not a large group of patients whose levels are in the area of the 6.0 percent A1c target of the intensive glycemic control group of the ACCORD trial. Nevertheless, if intensification of glycemic control becomes more prevalent using current regimens, there may be a susceptible group of patients at risk because of some genetic or toxic consequence of their diabetes or another factor. The Chair of the ACCORD study group has said that there may be a significant danger in attempting to lower A1c levels to values around the 6.4 percent achieved in the intensive treatment group in ACCORD.

At the same time, however, patients with type 2 diabetes and their physicians should consider the established benefits of glycemic control and recognize the progress that has already been made. It is very important to emphasize that several studies have shown the benefits of good glucose control on the microvascular complications of diabetes. Also, studies have shown the advantages of blood pressure control and intensified LDC cholesterol lowering in type 2 diabetes. If pursued collectively, these strategies should change the overall risk of microvascular and cardiovascular complications in diabetes. The 50-year data analysis of the Framingham study suggests that diabetes patients have had a decline in the CVD risk rate that parallels the major decline, but still remains 2-3 times higher, than the general population of non-diabetics--although there are some data suggesting that diabetes patients, particularly women, may not have done as well during the last decade. Other data accumulating from interventions that do not involve glycemic control indicate that much can be done for diabetes patients. Importantly, there is no evidence that the excess deaths seen in the intensive glycemic control group of the ACCORD trial would occur in individuals with recent-onset type 2 diabetes. In fact, it may be very important to do more studies in the earlier stages of type 2 diabetes to see if it is possible to prevent or reverse the deterioration in health that occurs over time, especially in populations with very high rates of diabetes, such as the American Indians or other high risk minority groups in the U.S.

VII. ADVISORY COUNCIL FORUM: Part 1

Update on Peer Review Enhancement
Dr. Lawrence Tabak
Director, National Institute of Dental and Craniofacial Research

Dr. Rodgers noted that Dr. Tabak's presentation would provide an update on the NIH peer review self-study that has resulted in an 88-page final draft report. Dr. Tabak has had a leadership role in

the internal and external working groups involved in the selfstudy. He previously briefed the NIDDK Council on this effort.

Dr. Tabak set the stage for his presentation by noting that the increasing breadth, complexity, and interdisciplinary nature of science creates new challenges for the peer review function, which is essential to the NIH mission. Funding trends can also aggravate stresses on the peer review system. In response to these factors, the NIH initiated a self-study of the peer review system with the goal of enhancing it. Since July 2007, the NIH self-study of peer review has proceeded through several phases, under the leadership of two working groups—one internal and one external. The charge of the NIH Director to the working groups was to find ways to fund the best science, by the best scientists, with the least administrative burden. However, it was recognized that the term "best"--when used in assessing research applications--is context-dependent, including many factors such as the scientific quality, public health impact, and mission relevance of the scientific proposals, as well as their relationship to the existing NIH portfolio.

The phases of the peer review self-study have included diagnosis of the issues; design of an implementation plan; and the start of phased implementation of several actions. The diagnosis phase involved broad outreach to the external and internal NIH communities, including five regional town hall meetings around the country, as well as a Request for Information that received a robust response. A dialogue was also begun with most of the National Advisory Councils. Based on these and other sources of input received, a Final Draft Report was submitted to the NIH Director issued on February 29, 2008. This report is on the NIH website at: http://enhancing-peer-review.nih.gov

Seven Challenges

The report articulates seven sets of challenges along with recommended actions to address them. The challenges include reducing the administrative burden on stakeholders; enhancing the rating system; enhancing the quality of both review and reviewers; optimizing support at different career stages; optimizing support for different types and approaches of science; reducing stress on the support system of science; and meeting the need for continuous review of peer review. Based on feedback, a skeletal framework for implementing all of the recommendations was provided to the NIH Director on April 15, 2008. The self-study is now in its final stages in which implementation approaches are being vetted in several ways, including a presentation by Dr. Zerhouni to the Peer Review Advisory Committee (PRAC) and by internal NIH discussions with the NIH Steering Committee members and other Institute and Center Directors. Discussions will also take place with several Study Section chairs and members of the Advisory Committee to the Director, NIH (ACD). In June, a public meeting is planned to provide details regarding the ways that some specific recommendations have been selected for further implementation.

Core Themes

The NIH has looked at the big picture to decide which of the major challenges need to be tackled first. In implementing changes, some general principles have been established to guide the process. The first general principle is to do no harm. The second principle is to continue to maximize the freedom of scientists to explore. A third is to place emphasis on a subset of changes that are most likely to add significant value to the system, but at a reasonable cost-benefit ratio. As a result of this process, four interdependent core themes have emerged.

Excellence of Reviewers: It is recognized that the excellence of peer review is directly correlated to the ability of the NIH to recruit, retain, and motivate the most accomplished, broad-minded, and creative scientists to serve on Study Sections. Therefore, key goals are to reduce the burden on reviewers, to recruit additional distinguished reviewers to serve on Study Sections, and to recognize

and compensate the efforts of distinguished NIH review service. The NIH wants to acknowledge those scientists whose efforts extend well beyond expectations in terms of their excellence in review service. It will also be important to use common best practices to enhance the training of NIH Scientific Review Officers, Study Section Chairs, and members of review panels.

Fairness and Clarity of Review: Peer review requires the consistent identification of the relative merit, potential for scientific and/or public health impact, and feasibility of research applications. Thus, the NIH seeks to enhance the process for providing applicants and NIH Program Officers alike with clear and purposeful review feedback through informative Summary Statements, and a rating system that is comparable across Study Sections and fields of science. To accomplish this, the NIH plans to modify the research application structure and to align it with a new rating system and Summary Statement format that will emphasize the five specific review criteria: (1) impact, (2) investigator, (3) innovation or originality, (4) project plan and feasibility, and (5) environment. In the new system each review criterion will be given its own score. The NIH plans to pilot new models of review, including the editorial board model—a two-stage system similar to the review process used for the publication of articles by scientific journals.

Support for Scientists at Different Stages of Their Careers: The peer review system clearly needs to provide an unbiased evaluation of applications from all scientists, irrespective of their disciplines or where they are in their career paths. Moreover, the NIH should not favor the funding of conservative scientific approaches at the expense of innovation and originality.

A major goal will be to reduce any bias in the review of early-stage investigators. For example, the NIH needs to ensure that there is no bias toward subsets of investigators regarding the opportunity for full discussion during the review process. This issue became apparent to the NIH when it observed the adaptation of Study Section behavior to changes in funding policy. When the Study Sections understood that the NIH was committed to funding more early-career investigators, the scores for these applicants began to drift upward, and an increasing percentage of their applications were left unscored--without the benefit of discussion. It has also become clear that a subset of investigators who had been considered "new," are very accomplished researchers with other sources of support--even though they may not have received an NIH R01 grant. In the future, the NIH will delineate those "new" investigators (new to NIH funding, but not to research success) from those who are truly early-stage in their careers, that is, within ten years from receipt of their last degree or clinical training. The NIH plans to continue its efforts to fund more new-to-NIH and early-stage investigators. An effort will also be made to expand transformative research pathways--for example, expanded use of the Eureka Award—and also to enhance the overall system used to support research.

A second example relates to the balancing of retrospective and prospective review. It is important to evaluate both the science produced and the science proposed. Recognizing that past performance is the best predictor of future success, the NIH has determined that the review of applications from established investigators--who have had the opportunity to establish a track record--will include increased emphasis on retrospective assessment.

Dr. Tabak noted that a third issue related to stages of a scientist's career concerns the success rates for initial submission of a research grant--the A0 submission--relative to the success rates for subsequently amended and resubmitted applications (A1 or A 2 applications), as previously mentioned by Dr. Rodgers. An analysis of data has shown that, over time, there has been a drop in A0 funding rates and an increase in the funding of applications at the stage of first or second resubmission (A1 or A2, respectively). Dr. Tabek showed several slides to illustrate the changes that have occurred. For example, in 1998, slightly over 60 percent of R01s-equivalent grants that were awarded were made in response to A0 applications. However, by 2007 the percentage of R01-equivalent grants made in response to A0 applications fell to about 30 percent. During this same 1998

to 2007 time period, the percentage of R01-equivalent grants made in response to A1 applications rose from slightly under 30 percent to nearly 40 percent. The corresponding percentage of R01-equivalent grants awarded in response to A2 applications rose from slightly under 10 percent to about 30 percent. Corollary data indicate that, in 1998, nearly all A0 applications at about the 15th percentile were funded. However, over time, an increasing number of resubmissions have been required (through 2006) for an investigator to obtain funding.

These changes have increased the inefficiency of the peer review system, which must deal with processing the resubmissions. Concerns have even been raised anecdotally that some investigators may be purposefully planning for poor scores on their initial applications, with the expectation that they will go through a resubmission process that will likely culminate in funding. Although the funding rates for resubmissions are high and improvements in the quality of some applications probably do occur, there may be a subset of applications that really do not need to undergo this iterative review process, which is burdensome to both investigators and reviewers. Moreover, it is not known if resubmissions produce better science. Thus, consideration has been given to the development of an NIH-wide policy statement regarding an intent to return to historical averages of funding rates for A0, A1 and A2 submissions.

Continuous Quality Control and Improvement for Peer Review: Continuous enhancement of the NIH peer review system needs to be based on rigorous and independent prospective evaluations that favor, rather than discourage, adaptive and innovative approaches to peer review and program management. The present self-study has identified steps the NIH will immediately begin to implement, along with actions that will not be pursued at this time. Dr. Tabak elaborated on a group of concepts that were considered during the self-study, but that are either not moving forward at all, or not in the form proposed.

- *Paying Reviewers for Their Time in Preparing for and Participating in the Review Process:* This idea is not being pursued because it probably would not make a great deal of difference in terms of recruiting and retaining excellent reviewers.
- *Relieving Reviewers of Administrative Reductions on Their Grants:* There is considerable unevenness in these reductions among the Institutes and Centers; therefore, this approach would have unintended disparate impacts.
- *Introducing a New Designation to Peer Review--"Not Recommended for Resubmission" (NRR):* This concept is based on the perspective that the science of some applications, no matter how much they are improved via the resubmission process, is unlikely to have a sufficient impact to warrant funding. Rather than having the investigator undergo the A1 and A2 process--and then possibly even change the content sufficiently to start the whole process over again with an A0 application--it may be better for the applicant to know at the outset that spending additional time and effort on the scientific concept will probably not result in funding. The NIH is not going to adopt this approach because the research community did not support it. Instead, by elaborating on the specific criteria that the reviewers will use and reflecting those criteria in the Summary Statements, the NIH will convey to the applicant information about his or her probability of eventual funding, without the starkness of an NRR designation.
- Permitting "Prebuttal" To Correct Factual Errors: Broadly endorsed, the general idea underlying this recommendation will be tested in a pilot manner through the two-stage, editorial-board model of review. However, this model will not be implemented extensively until the NIH has an opportunity to see how it works experimentally.
- *Overweighting the Research Environment for Early-stage Investigators:* While this concept had some support, it could introduce a bias against less research-intensive institutions.

- *Establishing Separate Reviews for New Investigators and for Clinical Research:* While the intent of this concept is to foster these two categories, its implementation could result in stigmatizing them.
- *Creating a New Mechanism for Transformative Team Science:* This action is not considered necessary at this time because of the existence of the Eureka Award, the Pioneer Award, and other similar mechanisms.
- *Considering all Applications as New (A0):* This idea met with great opposition in the research community.
- *Allowing NIH Salary Support for a Maximum of 50 Percent:* This action could favor some institutions more than others because of differences in the business models in academic institutions across the country.
- *Requiring a Minimum of 20 Percent Effort for Principal Investigators:* This idea raised enormous angst in the community, particularly among scientific professional organizations. While there is a need to determine whether investigators have sufficient time to realize the scientific aims of their grants, there could be unintended consequences because of differences in defining percent effort among academic research institutions. Therefore, the NIH will not pursue this particular route, but will seek alternative administrative approaches to ensure appropriate use and oversight of resources.

Currently, the NIH is beginning to discuss with stakeholders the parameters of the planned enhancements to the peer review system. The NIH will flesh out the details of various implementation strategies and Dr. Zerhouni will announce them in June to the Advisory Committee to the Director, NIH (ACD). He is also scheduled to have a commentary in *Science* in mid-June. For some enhancements, implementation can commence very quickly. Other changes may require more time for planning and execution. The NIH plans to evaluate the effects of the modifications that are introduced, as it indicated to the community at the beginning of the self-study process. It is expected that the results of those evaluations will ultimately lead to the development of new NIH policies.

Council Questions and Discussion

Has there been significant discussion about the length of research applications during this thoughtful self-study process? Dr. Tabak replied in the affirmative. As a result, the NIH will be implementing a shortened application for all R series research grants, for the F research training awards, and for the K research career and development awards. The precise length of the application is still under discussion; however, a seven-page application for R01 grants was recommended by a subset of the investigative community. Others favored a length of about fifteen pages. However, it was recognized that the presentation of complicated clinical trial proposals may need additional space. The final length will likely be between seven and fifteen pages--with an appendix for proposals that involve clinical trials, epidemiology and other areas requiring additional explication. When the final length is agreed upon for the R01 grant, the length of applications for other mechanisms will likely be scaled to it.

The report outlined the knotty problem of introducing a designation of "not recommended for resubmission (NRR)," which is not favored by the community for addressing the trends in A0, A1, and A2 applications. However, another difficult problem is the skew that is introduced to peer review by the use of ad hoc reviewers who only vote on occasion, in contrast to the continuity of review provided by regular Study Section members. What can be done to eliminate that problem, perhaps with mathematical approaches? Dr. Tabak responded that the NIH will be addressing both of these issues. With regard to the former, all applications will be scored in the future by use of five criteria that will provide meaningful, practical feedback to investigators without resorting to an NRR designation. For applications that do not receive further discussion, the applicants will at least receive

the average of the reviewers' scores on each of the five criteria. Thus, for example, they will have a sense of whether or not the potential scientific impact of their proposals was judged to be below an acceptable threshold. For applications that are considered further, the Study Section members will establish a global score that is informed by the scores on the individual criteria and the discussion about them, as led by assigned reviewers. The general consensus is that this process should not be driven by algorithms, but rather, that it should be informed by the results of peer review on the individual criteria. The NIH expects that these changes will help to address the issues raised.

The report is impressive and reflective of an incredible effort. Many of the approaches for which there is an action plan will be very positive. Two actions of particular note are efforts to address the unevenness of review, and also, to try to ensure funding for the most outstanding investigators. The increased focus on innovation is likewise extremely important. One question is whether some of the enhancements planned for Study Sections would lead to their being tasked with actual funding decisions? Also, what data exist regarding the degree of scattered results in the Study Sections? Dr. Tabak responded that the driver for the discussion about ranking applications at the conclusion of a Study Section meeting is the sense that there is unevenness in terms of the review of applications on the first day of a Study Section meeting *versus* the review of applications reviewed on the second day. Analysis shows that, if an investigator is among the first applicants reviewed, he or she will benefit. Many involved in the peer review self-study argued that a global re-examination and ranking of all the individual applications would enable the Study Section to provide a more even review process for the entire universe of applications it considers. Other ranking methodologies have been proposed, such as an up-front ranking. The NIH proposes to pilot different approaches to ranking. However, the new ranking process would not replace the vital role of National Advisory Councils in final funding decisions. While the NIH is trying to maximize its funding investments, including support for outstanding and innovative investigators, the agency also recognizes that the universities contribute enormous amounts of funding to the support of research. Because of the dynamics of the NIH budget-doubling period followed by a leveling-off period, many investigators are now at funding risk in many institutions. A dialogue should probably be established among stakeholders to come to grips with this issue so that ways can be found to sustain these investigators in their research careers.

Is there a way to reduce the burden on the peer review process by staggering the initiation of funding based on data showing that about 55 percent of applications will eventually be funded? Dr. Tabak replied that the NIH self-study included discussion of the relative value of having a funding queue so that investigators who were not within an Institute's or Center's payline but scored close to it would not have to reapply and undergo the peer review process again. In general, the National Advisory Councils favored this idea, and it is likely that it will be pursued at the level of the individual Institutes and Centers. Such an approach would greatly reduce the burden of peer review on both applicants and reviewers, while preserving the critically important role of the Councils in funding decisions.

Will there be a process to reconsider at some future point the recommendations from the self-study process that are not being implemented? What was the process for differentiating between those recommendations that would go forward and those that would not? What will happen with some of the more innovative suggestions, including the one about "Not Recommended for Resubmission"? In keeping with the last core theme regarding the need for continuous quality control and review of peer review, Dr. Tabak noted that the issues and recommendations not pursued at this time may be revisited in the future if the enhancements being implemented are not as effective as hoped. The NIH recognizes the frustrations that investigators experience when revised and resubmitted applications still do not receive funding. Investigators might be spared that process if they knew, from an NRR designation on their initial application, that there was little probability of their work being funded, even with revision. However, the NIH received substantial feedback from the research community in opposition to the NRR concept, particularly because it could dishearten investigators. The NIH will

therefore take a different approach to this issue through a more structured review built upon five explicit criteria and a Summary Statement in which the reviewers must address those criteria, with the impact of the application being a primary consideration. Thus, the applicant and the Program Officers at the Institutes and Centers will have much clearer feedback than they have had previously regarding whether the revision and resubmission of an application will improve its funding prospects. When the effects of this approach are analyzed through the continuous review of peer review, it is possible that the NIH could revisit previous recommendations about this issue or entertain suggestions for other, different approaches.

What about the cost to investigators of time spent rewriting grant applications—time that could be spent on doing the science? Wouldn't the NRR approach help avoid that problem? Dr. Tabak responded that the NRR approach was viewed as useful by the NIH, but that the community responded very negatively to it. However, as the issue of grant resubmissions continues to be discussed and the five criteria are rolled out, the NIH expects that investigators will realize that an application judged to have little potential for scientific impact will have little likelihood of funding upon re-review no matter how perfect the application may otherwise be. Thus, the effect of the five criteria is consistent with the underlying principle of NRR, without resorting to the use of that specific terminology.

Was any consideration given to whether there might be cost savings achieved from peer review enhancement that could be redirected to the budget available for funding research projects? Dr. Tabak said that this concept was considered extensively. Because the major cost of peer review is travel for the reviewers, the NIH will go forward with increased use of electronic-assisted reviews. However, face-to-face meetings of Study Section members cannot be completely eliminated for several reasons, including differences among scientific disciplines and some technical problems with video-enhanced reviews. The NIH hopes to make some modest investments in electronic-assisted reviews that may diminish the expense of travel.

VIII. ADVISORY COUNCIL FORUM: Part 2
NIH Roadmap for Medical Research

Roadmap Initiative Update
Dr. Philip Smith
Deputy Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, and
Co-Director, Office of Obesity Research

Dr. Smith reported that two new programs under the second cohort of the NIH Roadmap for Medical Research have begun to move forward: the Microbiome Project and the Epigenomics of Human Health and Disease Project. Both programs were highlighted at the February Council meeting. They are of great scientific interest to the NIDDK, which is actively participating in their management. Requests for Applications have been issued, and funding for the initial parts of the initiatives is expected to begin this year.

The NIH has also initiated a third wave of planning for Roadmap programs. New programs were recently recommended to the Directors of the Institutes and Centers, and several relate to specific interests of the NIDDK. Because concepts are still under consideration by the NIH Director, it will not be possible to report on them until final decisions are made.

New Roadmap Initiative Development Process
Dr. Betsy Wilder
Acting Associate Director
Office of Portfolio Analysis and Strategic Initiatives (OPASI), NIH

Dr. Wilder acknowledged the contributions of the NIDDK to keeping the Council apprised of Roadmap programs. It is important to NIH that Roadmap programs be based on community input. The Roadmap programs are intended to address severe, pressing needs within the scientific community without duplicating efforts in the Institutes and Centers. Importantly, Roadmap programs are intended to be transformative. Although it is difficult to predict transformation, approaches are being sought to further insightful decisions.

There are several groups that participate in the Roadmap process. At the NIH, these groups include:

- *NIH Leadership:* Collectively the 27 Institute and Center Directors make conceptual recommendations regarding concepts submitted for consideration. These recommendations are passed to the NIH Director for final approval.
- Director, Office of Portfolio Analysis and Strategic Initiatives: Under the authority of the NIH Director, the OPASI Director makes final decisions on detailed issues. His decisions are based heavily on the recommendations of a rotating group of three Institute and Center Directors and the OPASI Director called the ICOD. The ICOD is delegated the responsibility of reviewing programmatic details, such as approving RFAs and funding plans.
- *Working Groups:* Trans-NIH groups of program staff from the Institutes and Centers and from OPASI help to develop and implement new programs, and are responsible for managing ongoing ones. The primary workers in this process are the Institute and Center staff members, for whom OPASI serves as a supportive umbrella mechanism.

The development of Roadmap initiatives has involved input from many sources external and internal to the NIH, from portfolio analyses reflective of NIH current funding, from the Council on Councils, and from public meetings. The National Advisory Councils have a key role in informing NIH staff about pressing scientific needs in their respective research communities. A key mechanism for obtaining broad input has been and will continue to be the Request for Information (RFI). When NIH staff members submit ideas through an RFI, it is understood that they are reflecting extensive community input gathered in many ways. From such broad-based input, NIH staff members funnel ideas to OPASI, which, in turn, passes them along to senior program officials who review them for responsiveness to the Roadmap criteria. Are the ideas cross-cutting in scope, relevant to many diseases, relevant to the missions of the Institutes and Centers but not duplicative of their efforts? Do the ideas have the potential for being highly transformative? Although many ideas are potentially transformative, they need to be considered against the backdrop of the existing NIH scientific portfolio to see if they would help to fill research gaps. It is likewise important to identify the major hurdles to making scientific progress and the most effective ways to overcome them.

The Working Groups refine the submitted ideas into proposals for new programs, which are then sent to the Council of Councils, whose members include representatives from the National Advisory Councils of the Institutes and Centers. The Council of Councils meets in November and March and has two roles in the Roadmap process. First, in addition to participating in generating suggestions via the RFI, the Council of Councils can formulate and discuss much broader ideas, especially new approaches to be tested via the Roadmap and new ways to foster innovation and transformation. Second, the Council of Councils reviews proposals at its annual Fall meeting prior to the NIH leadership's selection process in February. If the Council deems that a proposal is not responsive to Roadmap criteria, it can provide comments and guidance regarding how it could be made responsive. Following The Council of Council's concept clearance, the proposals are sent to the NIH leadership for final approval.

The NIH would like to amplify the needs assessment process by the community because it is a critical part of developing new Roadmap programs. The currently active Request for Information, which is open until June 2, 2008, is the first means of needs assessment for new concepts. Moreover, for NIH staff members, the RFI will now be the only route for submitting new ideas for the next Roadmap cycle. Ideas from the National Advisory Councils will also need to come in through the RFI. The NIH expects that workshops, surveys and more detailed RFIs will be undertaken over the course of the summer by NIH teams before the most compelling of the submitted ideas are developed fully into proposals for concept clearance.

There is an increasing need for portfolio analysis to assess the research areas that are currently being funded by NIH. These analyses are an important context for the consideration of ideas submitted for possible Roadmap funding. The OPASI is working to develop new and more automated methods of portfolio analysis, but will also retain the human element in the assessment process.

In summary, the decision-making of the NIH leadership in the next stage of the Roadmap life cycle will be informed by input from many sources: responses to the RFI; the Council of Councils; analysis of the existing NIH research portfolio; and continuing assessment of community needs. Ideas submitted through the RFI solicitation mechanism will go to a group of senior NIH staff members, who will identify those that will go forward for further development into proposals over the summer. These proposals will be submitted to the Council of Councils in the Fall. Finally, the proposals will be considered by the IC Directors and NIH Director at their annual February retreat.

Council Questions and Discussion

What are the challenges to having truly innovative ideas identified and supported through these mechanisms? Dr. Wilder replied that the challenges are huge, but the process involves a great deal of consensus building. Currently, The Roadmap has programs that are very open-ended in their scientific content, such as the Pioneer Awards and the New Innovator Awards. Because it is difficult to recognize true innovation in advance, these types of mechanisms encourage the community to submit outstanding ideas and the NIH will find a way to fund them. These types of program have a heavy emphasis on the past research achievements of the applicants. The NIH is also discussing the possibility of having another open-ended approach that is based more on the project than on the investigator. There can be a tension between the goal of funding innovative ideas and the goal of addressing the specific needs that cut across many disease areas and the individual missions of the Institutes and Centers. Currently, there is a single funding pool for Roadmap efforts, and ideas that may be weighted more toward one direction or another must compete within that funding envelope.

Is it important to have clarity about which ideas are responsive to shared research needs versus which ones are innovative approaches that fall beyond the domain of any single IC? Dr. Wilder responded that clarity about these different types of ideas is definitely important. However, targeting a specific allocation of funds for these different types of projects within the overall Roadmap funding envelope would probably not be well- received by the community.

How many concepts are submitted? How do you ensure that the individuals who screen the submitted ideas and filter out those that will not receive further consideration have sufficient scientific expertise to do that? Dr. Wilder said that the last time ideas were solicited, over 300 were submitted. The Institute and Center Directors triaged the ideas, with the assistance of a group of senior program staff members who provided their views about responsiveness of the ideas to the Roadmap criteria. However, for the next cycle of ideas, the Directors will designate a member of their scientific staff to represent them in this process. Like the Directors, their delegates will have broad knowledge of the research portfolios of their respective Institutes and Centers. For the NIDDK, Dr. Rodgers has nominated Dr. Philip Smith. Thus, collectively, the process should reflect the same type of expertise

that is possessed by the Institute and Center Directors as a whole. It is also important to keep in mind that the RFI requests the submission of very broad conceptual problems and a way to approach them. Hence the filtering process is at a conceptual level that does not require scientific expertise about the details of the proposed ideas. Dr. Rodgers commented on the long, detailed, and deliberative process through which Roadmap ideas are broadly vetted. Extensive time is spent by the NIH scientific staff in performing portfolio analyses and in considering whether the submitted ideas represent transformative research that would unlikely be pursued by a single Institute or Center. Dr. Rodgers noted that the member of the NIDDK National Advisory Council who serves on the NIH Council of Councils is Dr. Juanita Merchant, who very recently was also recognized by the American Gastroenterological Association with an award for her outstanding mentorship in science. After the Council of Councils becomes fully operational, the NIDDK will invite Dr. Merchant to make a presentation to the NIDDK Council about its activities relative to the Roadmap.

The Roadmap process is logical, inclusive, and exciting. What is the cost of the Roadmap initiatives? Is there a danger that the Roadmap will raise unrealistic funding expectations in the research community? There is a growing cynicism about the ability of NIH to support costly initiatives given its current budget realities. For example, in one Roadmap initiative--the Clinical Translational Science Awards (CTSAs)—the awarded budgets were dramatically reduced from the original requests. In such circumstances, the investigators cannot deliver what they have proposed. What other research may need to be sacrificed if all the excellent Roadmap ideas are funded and come to fruition? Dr. Wilder replied that the total Roadmap budget is currently $500 million. Dr. Rodgers noted that the initial funding of the Roadmap included the NIH Director's funds and transfers from the ICs. However, by legislation, budgetary resources for support of the Common Fund, which includes the Roadmap, are now provided through a direct, separate congressional appropriation for that purpose. Hence, the ICs are no longer transferring funds from their own specific appropriations to support Roadmap activities and the issue of opportunity costs and trade-offs does not really arise. The ICs can now use the funds they would have transferred to the Roadmap initiative for other research activities. With regard to the CTSA program, Dr. Wilder noted that this initiative is jointly funded by the National Center for Research Resources and the Roadmap, within a framework developed in conjunction with congressional staff input. Because the CTSA program is new, the NIH will need to see how it is functioning before it can determine the level of future budgetary commitments may be appropriate based on that program assessment. Dr. Rodgers also commented that the CTSAs are being rolled out in a relatively fast-paced, two-phase exploratory approach. Efforts are being made to reach the number of CTSAs that NIH set as a goal; however, accomplishing that goal within a fixed budgetary envelope is requiring some funding adjustments. Importantly, there is a recognition that many CTSAs are at institutions that house large clinical efforts funded by the NIH through other means. The ICs have been asked to identify one or two leaders of clinical research at institutions that have CTSA awards to see whether it may be possible to realize economies of scale if funded investigators could be involved in these CTSAs. The NIDDK has two such leaders who are Principal Investigators on currently funded CTSAs whom it would like to invite to a future Council meeting to present their ideas and seek feedback on ways to enrich and synergize the CTSAs with NIDDK's ongoing clinical research activities. Dr. Alving, the Director of NCRR, spoke to the Council about the CTSA program previously and it may be an appropriate time to invite her back for an update on the goals and directions of the program.

IX. SCIENTIFIC PRESENTATION
RNAi-based Therapeutic Strategies for Metabolic and Inflammatory Diseases
Dr. Michael Czech

Dr. Rodgers introduced Dr. Michael Czech, Professor and Chair of Molecular Medicine and Professor of Biochemistry and Molecular Pharmacology at the University of Massachusetts Medical School.

Dr. Czech gave an overview of his laboratory's work developing gene silencing strategies and demonstrated the therapeutic potential for strategies using Glucan Encapsulated siRNA Particles.

X. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 2,001 grant applications, requesting support of $449,325,793 were reviewed for consideration at the May 23, 2008 meeting. Funding for these 2,001applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 1,015 applications requesting $244,050,102 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 23, 2008 meeting.

XI. ADJOURNMENT

Dr. Rodgers thanked the Council members for their attendance and valuable discussion. There being no other business, the 177th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m., May 23rd, 2008.

I hereby certify that to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases,
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

(Approved Minutes are available online at
http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/Meetings/Default)

Travel Expenses and Reimbursement

Allowable consultant expenses for members of NDDKAC are round-trip transportation (from home to Bethesda, Maryland, and back), ground transportation (taxi fares, parking, tolls, etc.), hotel (Government room rate and associated taxes), and per diem costs. A consultant fee is paid to the Council member for each day or fraction of a day spent on official duty.

Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is $0.585 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently $64.00 per day for the Washington, D.C., metropolitan area. You will receive ¾ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. A consultant fee is paid to the Council member for each day or fraction of a day spent on official duty.

Travel Instructions

Omega World Travel will make a "Courtesy Reservation" and then it is the Council member's responsibility to contact Omega Travel at 1-800-253-1098 to confirm/change the travel reservation. All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. If not using Omega World Travel, travelers will be reimbursed for transportation after the Council meeting. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

Hotel Information

You will receive hotel reservation information prior to the meeting. It is necessary for Council members to call the hotel and reserve a room with their credit card. Ask for the block of rooms reserved for the NIH/NIDDK meeting. Also please confirm your check-in and check-out dates, especially if arriving late.

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include receipts for taxi fares, tolls, parking fees, the original airline ticket stub, plus the original hotel bill. Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days.

Travel Expense forms and receipts should be sent to:

Dora A. Abankwah, Assistant to Director
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 713A
6707 Democracy Boulevard
Bethesda, MD 20892-5452

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket $_____
- **Original Hotel** itemized receipt:
  - Room Rate $_____
  - Hotel Taxes $_____
  - Phone Calls ($5.00 per day are reimbursable) $_____
- Other travel-related receipts **over $75.00** $_____
- Rental car (reimbursement must be pre-approved) $_____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x 55 cents) $_____
- Parking Fees $_____
- Taxis:
  - From Residence to Terminal $_____
  - From Terminal to Hotel $_____
  - From NIH Campus to Terminal $_____
  - From Terminal to Residence $_____
  - Other $_____
- Tolls $_____
- Other miscellaneous expenses $_____

  (Please describe:_____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of $64.00 per day. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

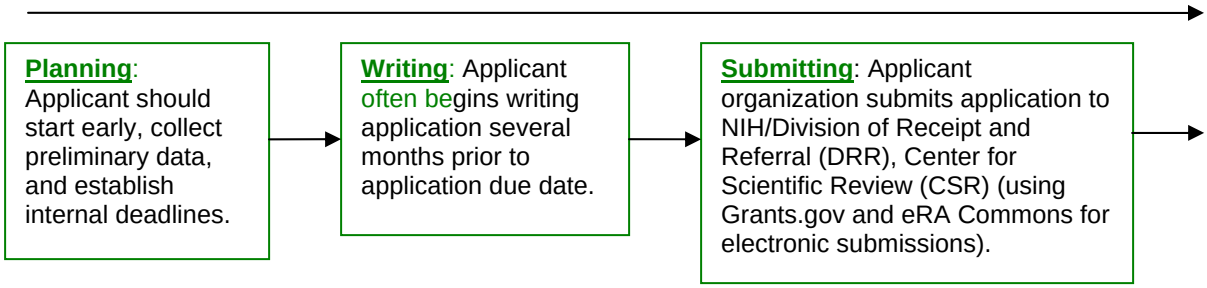
SIGNATURE: _____

DATE: _____

Grants Process At-A-Glance

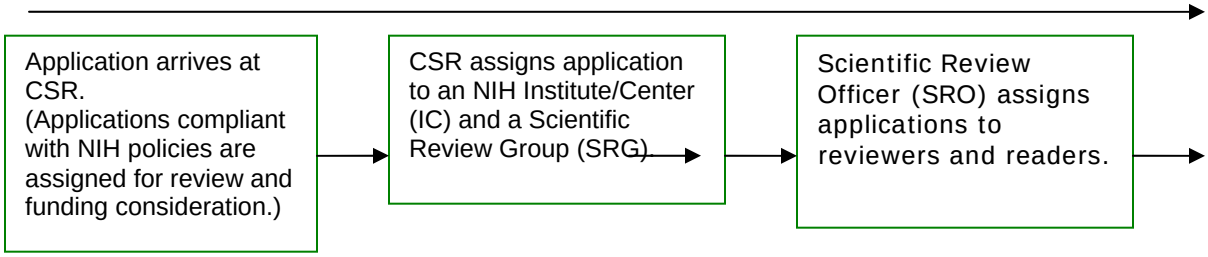
The following NIH "Grants Process At-A-Glance" chart is provided as a sample of the general time element necessary for a competing application to proceed from Receipt and Referral through the Peer Review process to negotiation and award.

Planning, Writing, Submitting



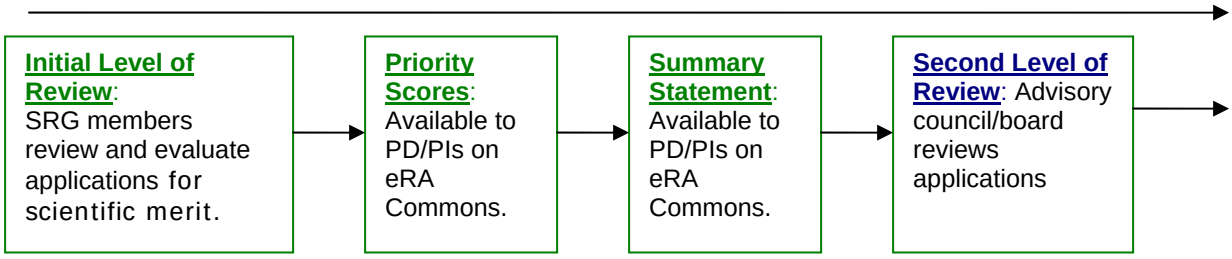
Receipt and Referral

Months 1 to 3



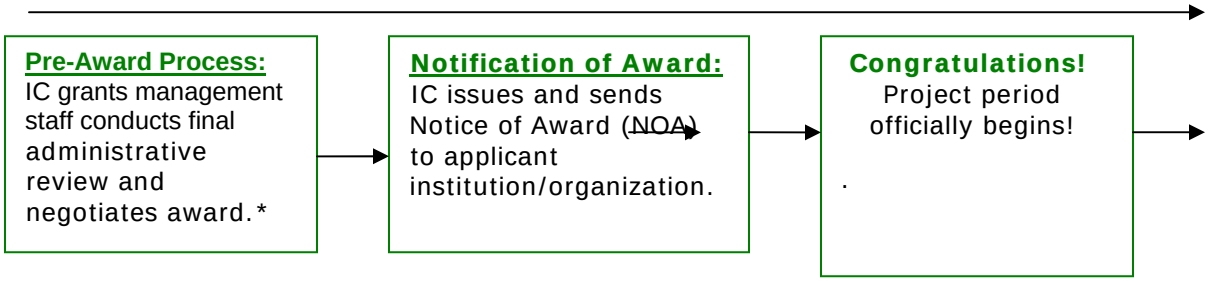
Peer Review

Months 4 to 8



Award (*Requests additional information needed just-in-time for award.)

Months 9 to10

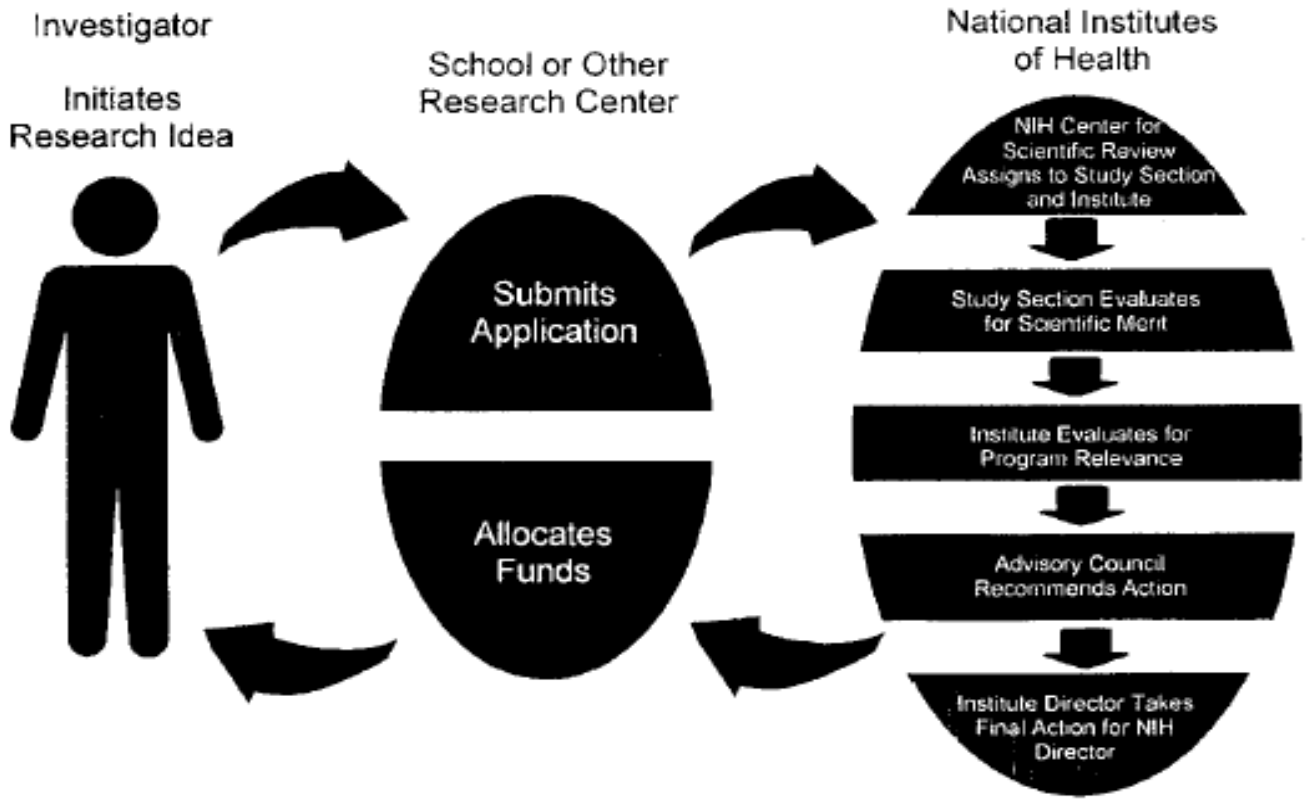


Post-Award Management

Administrative and fiscal monitoring, reporting, and compliance.

Note: Timeline is based on the standard grants process. It does not reflect a shorter timeframe for grants undergoing expedited review.

Review Process From Application to Award



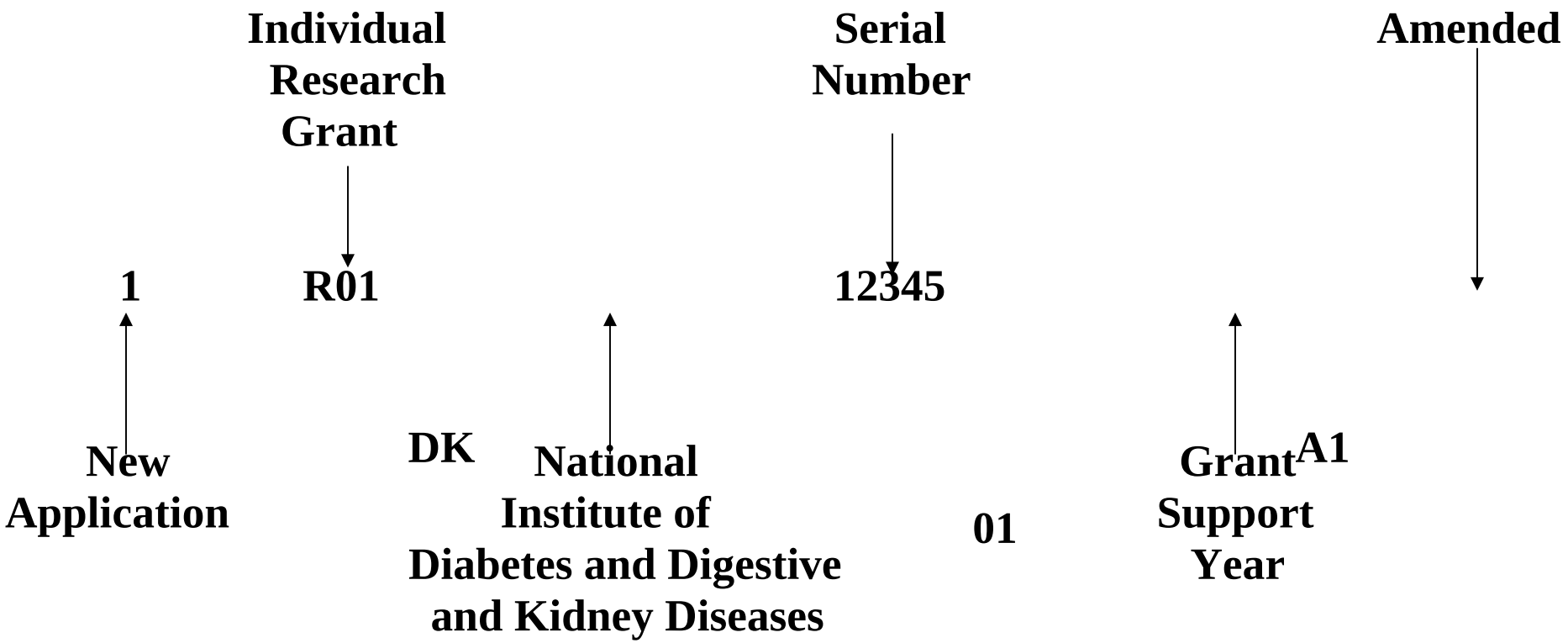
NIH Grant Receipt, Review, and Award Schedule

Jan-May **May-Sept** **Sept-Jan**	**Receipt Dates**
June-July **Oct-Nov** **Feb-Mar**	**Review Dates**
Sept-Oct **Jan-Feb** **May-June**	**National Advisory Council/Board Dates**
Dec1 **Apr 1** **July 1**	**Earliest Possible Beginning Date**

NIH Funding Instruments

Grant (NIH as Patron)	Cooperative Agreement (NIH as Partner)	Contract (NIH as Purchaser)
Project Conceived by Investigator	Project Conceived by Investigator or NIH	Project Conceived by NIH
NIH Supports or Assists	NIH Supports or Assists	NIH Acquires Services or Product
Performer Discusses Details and Retains Scientific Control	NIH Participates in Direction	NIH Exercises Direction and Control
NIH Maintains Cognizance	NIH Monitors	NIH Closely Monitors
Accomplishes a Public Purpose	Accomplishes a Public Purpose	For the Direct Benefit of the Government

Sample Application Number

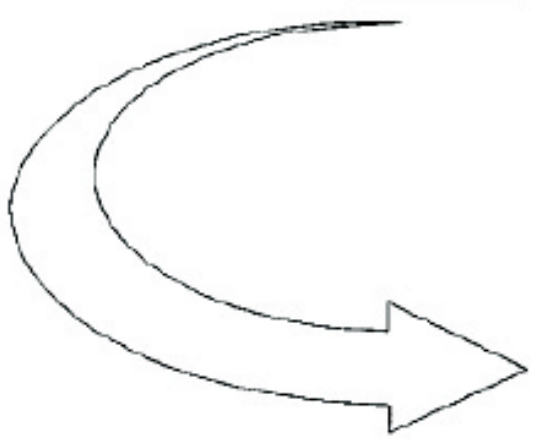


Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award



Second Level of Review

Council

- Assesses quality of SRG Review of Grant Applications (*See Advisory Council Voting Options)*
- Makes Recommendations to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Second Level of Review: Advisory Council Voting Options

- Concurrence with study section action
- Modification of study section action
- Deferral for re-review

NIDDK Makes Funding Decisions Based on:

- Scientific merit
- Program considerations
- Availability of funds

Review Procedures for Initial Review (Scientific Review Group Meetings)

The guiding principles for the initial review of research project grant applications are based on the Public Health Service (PHS) Scientific Peer Review Regulations that state that peer review groups are to make recommendations concerning the scientific merit of applications. The specific criteria used to assess the merit of research project grant applications will vary with types of applications reviewed, such as Investigator Initiated Research Project Grants (R01), Academic Research Enhancement Awards (R15), the National Research Service Awards (F32, F33, etc.), Small Business Innovation Research Grants, and so forth.

For the review of investigator-initiated research grant applications (e.g., R01 and R15), a streamlined procedure will be employed to determine whether the applications assigned to a study section are in the upper or lower half. This procedure is described in the document CSR Streamlined Review Procedures (http://www.csr.nih.gov/review/streamln.htm). Prior to the meeting of the study section, reviewers will be asked to identify applications that they feel are not in the upper half and will consequently not be discussed at the study section meeting. If two reviewers/discussants agree that an application is not in the upper half, it will be designated as such, and a list prepared by the SRA identifying proposed applications not in the upper half will then be sent to reviewers a few days prior to the study section meeting. After seeing this list any review group member not in conflict may disagree and identify an application that he/she believes is in the upper half and, therefore, should receive full discussion. At the beginning of the meeting, the list will be read aloud for final concurrence by the entire study section. If any member of the review group not in conflict questions the rating or wishes to comment on the application, it will be discussed and considered by the entire review group in the normal sequence of review.

The Chairperson of the scientific review group introduces each application designated for discussion and calls upon the individuals assigned by the SRA to present their evaluations. The assigned discussants are then called upon for their comments and group discussion follows. If prior to substantial discussion the scientific review group determines that the application being discussed should actually not be placed in the upper half, it may recommend that the application not be scored. Such a designation requires unanimous agreement of the scientific review group. Otherwise, after sufficient discussion has ensued, the Chairperson calls for a priority rating to be assigned to the application. Ratings will be assigned by regularly appointed members of the scientific review group and by those serving as temporary members. Reviewers are encouraged not to abstain. However, a reviewer who feels unable to assess the merit of an application, as evidenced by his/her prior discussion or recommendation for deferral, should mark the vote sheet "AB".

In addition, if there are comments or serious concerns regarding the use of human subjects or animal welfare or biohazards, a motion may be initiated that the application should be coded to reflect these comments or concerns, and an appropriate note will be included in the summary statement.

If additional information is needed before a review group can make a recommendation, a motion for **deferral** may be entertained. The review group may, by majority vote, defer an application for additional information or, if information necessary to evaluate the application can be obtained only by visual inspection of the facilities, for a project site visit. Any member may nominate an application for deferral.

Numerical Rating

Each scored application is assigned a single, global score that reflects the overall impact that the project could have on the field based on consideration of the five review criteria (significance, approach, innovation, investigator, and environment), with the emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. The best possible priority score is 100 and the worst is 500. Individual reviewers mark scores to two significant figures, e.g., 2.2, and the individual scores are averaged and then multiplied by 100 to yield a single overall score for each scored application, e.g., 253. Abstaining members and those not present during the discussion do not assign a numerical rating and are not counted in calculating the average of the individual ratings. Reviewers are asked to recommend that half the applications not be scored and to spread final scores to achieve a median score of 300. (Any member of the scientific review group may request that an application be scored, in which case all members must score the application.) To the extent that the study section does not score some applications, the scoring range is altered. If half of the applications are not scored, then the remaining applications should be scored from 100-300. If only 25% of the applications are not scored then the remaining applications should be scored from 100-400.

Budget

The budget recommendation should be based upon the appropriateness of direct costs for the proposed research for each year of support requested. Attention should be given to the need for all personnel listed in the application and their percent effort in relation to the scope of works. Reviewers should keep in mind the applicant’s ability to move funds amongst budget categories, therefore, the appropriateness of the total budget and the requested duration of support in relation to the research proposed should be emphasized.

Reviewers may identify areas of potential overlap with other supported research. However, potential overlap may be neither a reason for altering the budget nor may it affect the priority score. Information regarding potential overlap is included in the Scientific Review Administrator's note at the end of the summary statement.

NIH Enhanced Peer Review Process

Overview

The National Institutes of Health (NIH) has a longstanding history of supporting the most promising and meritorious biomedical and behavioral research using a broad range of approaches, strategies and mechanisms. While the world-renowned peer review system is the cornerstone of NIH, the increasing breadth, complexity, and interdisciplinary nature of modern research has created many challenges and necessitated a more formal review of the NIH peer review system.

To address these challenges, in June 2007, the NIH initiated the effort to formally review the NIH peer review system. External and internal working groups deliberated on challenges and recommendations regarding enhancements to the review system. Input was sought and received, with significant dialogue, from both internal and external communities.

In March 2008, NIH announced the end of a year-long diagnostic phase and release of the final report. The report, drafted by the Advisory Committee to the Director and the NIH Steering Committee, identified the most significant challenges and proposed recommendations that would enhance this system of peer review in the most transformative manner. Recommendations were developed with the overarching goal to:

Fund the best science, by the best scientists,
with the least amount of administrative burden.

Phases of Process

Diagnostic Phase

The diagnostic phase involved an in-depth evaluation of the current NIH peer review system. In June 2007, Dr. Zerhouni, established two working groups:

- Externally – The Advisory Committee to the Director Working Group (ACD WG) co-chaired by Dr. Keith Yamamoto of the University of California, San Francisco, and Dr. Lawrence Tabak, Director of the NIH National Institute of Dental and Craniofacial Research (NIDCR); and
- Internally – The Steering Committee Working Group (SC WG) co-chaired by Dr. Tabak and Dr. Jeremy Berg, Director of the NIH National Institute of General Medical Sciences (NIGMS).

The working groups solicited formal input from key stakeholders and deliberated on challenges and recommendations. The Final Draft Report (PDF - 1.61 MB) issued February 29, 2008, documents the outcome of the diagnostic phase and describes recommendations.

Design Implementation Phase

In March 2008, Dr. Zerhouni established the Steering Committee Peer Review Implementation Group to draft implementation plans for each recommended action. The committee convened subgroups led by Drs. Berg, Tabak and Story Landis, Director of the National Institute of Neurological Disorders and Stroke (NINDS). Subgroup membership consisted of NIH program and review officers, planning and evaluation experts and statisticians. Feedback was solicited from both NIH internal and external communities. This feedback, together with careful consideration of the pros and cons of both individual and combined recommendations, informed decisions on enhancements to the peer review system.

On June 6th, 2008, Dr. Zerhouni announced the Peer Review Enhancements and Implementation Plan (see the Press Release) and Dr. Tabak presented the Implementation Plan to the Advisory Committee to the Director (ACD). For detailed information on the Implementation Plan please see Slides (PDF - 534 KB).

The Implementation Plan is organized into the following priority areas:

- **Priority 1 – Engage the Best Reviewers -** The excellence of peer review is directly correlated with the ability to recruit and retain the most accomplished, broad-thinking, and creative scientists to serve on NIH study sections.
- **Priority 2 – Quality & Transparency of Review -** The peer review process must strive for maximum clarity, fairness, and consistency and help applicants determine a best course of action once reviewed. The process of review should focus on the potential impact, originality, and feasibility of the proposed research.
- **Priority 3 – Provide Balanced and Fair Reviews Across Scientific Fields and Career Stages -** Peer review should fairly evaluate proposals from all scientists, regardless of their career stage or discipline, and avoid bias towards more conservative and proven approaches at the expense of innovation and originality.
- **Priority 4 – Continuous Review of Peer Review -** The last priority is to develop a permanent process for continuous review of peer review. Peer review should continuously adapt itself to the evolution of science. The NIH peer review process will commit to a continuous quality control and improvement process based on a rigorous and independent prospective evaluation that favors innovative approaches to review and program management.

Begin Phased Implementation of Selected Actions

In July 2008, Dr. Zerhouni established a Peer Review Oversight Committee (PROC) (PDF - 35 KB) to initiate implementation. The PROC, chaired by NIH Deputy Director, Dr. Raynard Kington (now Acting Director, NIH), established subgroups consisting of NIH program, review, grants management, and evaluation staff to assist with the implementation effort.

On September 12, 2008, the PROC and subgroup chairs presented to Dr. Zerhouni the first of the preliminary implementation plans for the 2009 through 2010 calendar years

Areas of Implementation

The final set of recommendations is organized into the following four priority areas.

- **Engage the Best Reviewers**
  - Providing Benefits for Reviewers. In 2009, new reviewers will be given additional flexibility regarding their tour of duty, and other efforts will be undertaken to improve retention of standing review members.
  - Recruiting the Best Reviewers. A toolkit incorporating best practices for recruiting reviewers will be made available to all ICs in 2009.
  - Enhancing Reviewer Training. In spring 2009, training will be available to reviewers and SROs related to the changes in peer review.
  - Allowing Flexibility through Virtual Reviews. Pilots will be conducted in 2009 on the feasibility of using high-bandwidth support for review meetings to provide reviewers greater flexibility and alternatives for in-person meetings.
- **Improve the Quality & Transparency of Review**
  - Improving Scoring Transparency & Scale. In 2009, streamlined applications will receive a preliminary score**.**
  - Providing Scores for Streamlined Applications. Shorter (12-page research plan) R01 applications (with other activity codes scaled appropriately) will be restructured to align with review criteria for January 2010 receipt dates.
  - Shortening and Restructuring Applications
- **Ensure Balanced & Fair Reviews Across Scientific Fields & Career Stages, & Reduce Administrative Burden**
  - Funding the Best Science Earlier. To ensure that the largest number of high-quality and meritorious applications receive funding earlier and to improve system efficiency, the NIH will enhance success rates of new and resubmitted applications by decreasing the number of allowed grant application resubmissions (amendments) from two to one.
  - Clustering Applications in Review. In 2009, where possible, the NIH will cluster new investigator applications (including Early Stage Investigators) for review. The same approach will be considered for clinical research applications.
  - Early Stage and New Investigator Policies
- **Continuous Review of Peer Review**

Enhancing Peer Review at NIH Home Page: http://enhancing-peer-review.nih.gov/index.html

Enhancing Peer Review: The NIH Announces New Scoring Procedures for Evaluation of Research Applications Received for Potential FY2010 Funding

Notice Number: NOT-OD-09-024

Key Dates

Release Date: December 2, 2008

Issued by

National Institutes of Health (NIH), (http://www.nih.gov)

Background

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system. In June 2007, the NIH initiated a formal, agency-wide effort to review the NIH peer review system (http://enhancing-peer-review.nih.gov/). After careful deliberation and consideration of the recommendations resulting from this year-long effort, a number of key actions will be implemented in the NIH peer review system.

In current practice, each scored application is assigned a single, overall priority score that reflects the consideration of all review criteria. Individual reviewers assign scores on a 1 to 5 scale in 0.1 increments (e.g., 2.2), resulting in 41 possible rating discriminations for reviewers to make. The reviewers' individual scores then are averaged and multiplied by 100 to yield a single overall priority score for each scored application (e.g., 253).

Although this rating system has served the NIH and the research community well, several concerns led the NIH to consider a revised rating system for grant applications. Making 41 discriminations is difficult for reviewers to do reliably, and scores increasingly have become compressed toward the positive end of the scale. In addition, by averaging reviewer scores and multiplying by 100, the resulting priority score appears to have more precision than it actually has. To address these concerns, the NIH considered scoring systems with fewer rating options to increase potential reliability and with sufficient range and appropriate anchors to encourage reviewers to use the full scale. To increase transparency, the NIH also considered methods to

communicate ratings from assigned reviewers even when the application is streamlined and not discussed, or discussed and scored by the full committee.

Additional information is available in Guide Notices NOT-OD-09-023 "Enhancing Peer Review: The NIH Announces Updated Implementation Timeline" and NOT-OD-09-025 "Enhancing Peer Review: The NIH Announces Enhanced Review Criteria for Evaluation of Research Applications Received for Potential FY2010 Funding".

Implementation

New Scoring System. The new scoring system will be effective for all applications for research grants and cooperative agreements that are submitted for funding consideration for fiscal year 2010 (FY2010) and thereafter. The first standing due date for FY2010 is January 25, 2009; the new scoring system will be used for applications submitted in response to Parent Announcements and Program Announcements, including PARs and PASs published before or after this Guide Notice. An important aspect of the implementation of the new scoring system is to use it in a consistent manner for applications considered in a given fiscal year. Therefore, some RFAs and PARs for funding consideration in FY2010 have due dates before January 25, 2009, and responses to those will be evaluated using the new scoring system. Likewise some RFAs and PARs for FY2009 have due dates after January 25, 2009, and responses to those will be evaluated using the present scoring system.

The new scoring system will utilize a 9-point rating scale (1 = exceptional; 9 = poor). Although a 7-point scale was planned initially, a 9-point scale was selected based on the desire for a scale with sufficient range. The NIH also has prior experience with the distribution of scores from a 9-point scale, based on data on the 1-5 scale when only 0.5 increments were allowed[1]. Moreover, prior recommendations from measurement and decision science experts regarding the scoring system suggested that an 8 to 11 point scale is appropriate[2].

Not Recommended for Further Consideration. An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

Percentile Rankings. Percentile rankings will be calculated anew, starting with scores from the May 2009 cycle of review, and reported to the nearest whole number.

Scores for Individual Criteria. Before the review meeting, each reviewer and discussant assigned to an application will give a separate score for each of five core review criteria (Significance, Investigator(s),

Innovation, Approach, and Environment). For all applications, even those not discussed by the full committee, the scores of the assigned reviewers and discussant(s) for these criteria will be reported individually on the summary statement.

Priority Scores – Discussed Applications. Before the review meeting, each reviewer and discussant assigned to an application will give a preliminary impact score for that application. The preliminary impact scores will be used to determine which applications will be discussed. For each application that is discussed, a final impact score will be given by each eligible committee member (without conflicts of interest). Each member's impact score will reflect his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than a weighted average applied to the reviewer's scores given to each criterion (see above).

The overall impact score for each discussed application will be determined by calculating the mean score from all the eligible members' impact scores, and multiplying the average by 10; the overall impact score will be reported on the summary statement. Thus, the 81 possible overall impact scores will range from 10 - 90. (Overall impact scores will not be reported for applications that are not discussed.)

Funding Decisions. The new scoring system may produce more applications with identical scores ("tie" scores). Thus, other important factors, such as mission relevance and portfolio balance, will be considered in making funding decisions when grant applications are considered essentially equivalent on overall impact, based on reviewer ratings.

[1]Report of the Committee on Rating of Grant Applications (May 17, 1996) (http://grants.nih.gov/grants/peer/rga.pdf)

[2]Cicchetti, D.V., Showalter, D., and Tyrer, P.J. (1985) The effect of number of rating scale categories on levels of interrater reliability: A Monte Carlo investigation. *Appl. Psych. Meas.* **9:** 31-36.

Inquiries

Questions should be directed to EnhancingPeerReview@mail.nih.gov.
For more information on NIH's Enhancing Peer Review effort visit http://enhancing-peer-review.nih.gov/.

Enhancing Peer Review: The NIH Announces Enhanced Review Criteria for Evaluation of Research Applications Received for Potential FY2010 Funding

Notice Number: NOT-OD-09-025

Key Dates

Release Date: December 2, 2008

Issued by

National Institutes of Health (NIH), (http://www.nih.gov)

Background

In June 2007, the NIH initiated a formal, agency-wide effort to review the NIH peer review system (http://enhancing-peer-review.nih.gov/). After careful deliberation and consideration of the recommendations resulting from this year-long effort, a number of key actions will be implemented in the NIH peer review system. These actions include the implementation of enhanced review criteria for evaluating the scientific and technical merit of applications submitted to the NIH for grants or cooperative agreements to support biomedical or behavioral research.

Additional information is available in Guide Notices NOT-OD-09-023 "Enhancing Peer Review: The NIH Announces Updated Implementation Timeline" and NOT-OD-09-024 "Enhancing Peer Review: The NIH Announces New Scoring Procedures for Evaluation of Research Applications Received for Potential FY2010 Funding".

The enhanced criteria will replace the review criteria adopted October 12, 2004 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html) and modified May 11, 2006 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-069.html). A side-by-side comparison of the enhanced review criteria described below, and the criteria that will be replaced, is available on the OER website (http://grants.nih.gov/grants/peer/side_by_side_comparison.doc).

Implementation

The enhanced review criteria (below) will be effective for all applications for research grants and cooperative agreements that are submitted for funding consideration for fiscal year 2010 (FY2010) and thereafter. The first standing due date for FY2010 is January 25, 2009; the enhanced criteria will be used for applications submitted in response to Parent Announcements and Program Announcements, including PARs and PASs published before or after this Guide Notice. An important aspect of the implementation of the enhanced

criteria is to use them in a consistent manner for applications considered in a given fiscal year. Therefore, some RFAs and PARs for funding consideration in FY2010 have due dates before January 25, 2009 and responses to these will be evaluated using the enhanced criteria. Likewise some RFAs and PARs for FY2009 have due dates after January 25, 2009 and responses to those will be evaluated using the present criteria. RFAs and some PARs may include additional review criteria and considerations that are related to specific requirements of the RFA or PAR.

These enhanced criteria may not be applicable for some other types of applications (e.g., construction grants, fellowship applications). Criteria for these other programs will be described in the Funding Opportunity Announcements (FOAs).

Enhanced Review Criteria

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact. Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Core Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items**.

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species,

strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Additional Review Considerations. As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Select Agent Research. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Applications from Foreign Organizations. Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or

environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and 3) Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

Inquiries

Questions should be directed to:

Sally A. Amero, Ph.D.
NIH Review Policy Officer
OD/OER/ODP
National Institutes of Health
6705 Rockledge Drive, Room 3520
Bethesda, MD 20892
Telephone: (301) 435-1418
Email: ameros@od.nih.gov

Or send an email to EnhancingPeerReview@mail.nih.gov.

For more information on NIH's Enhancing Peer Review effort visit http://enhancing-peer-review.nih.gov/.

Second-Level Review Procedures

Second-level review is the assessment of the quality of the initial review of grant applications. By law, NIDDK's Advisory Council must recommend an application before the Institute can fund it. Second-level review is **not a second scientific review**. Rather, the Council looks at applications with potential barriers to funding such as human subjects and animal concerns or special circumstances such as foreign applications and renewal applications requesting more money than the limit.

The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote. When Council recommends an application for funding, that doesn't necessarily mean it will receive an award. NIDDK makes the final decision.

Recommendation Process

- NIDDK program staff members examine application priority scores and consider these against the IC's needs.
- Program staff provide a grant-funding plan to the Advisory Council.
- The Advisory Council also considers the IC's goals and needs and advises the IC director.
- The IC director makes final funding decisions based on staff and Advisory Council/Board advice.

Post-Review

- **Not Funded – What Next?**
  The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, NIH has resources available to help applicants prepare a possible application revision and resubmission. Applications in response to a specific initiative with set aside money typically cannot be resubmitted, but you the program officer should be consulted about next steps.
- **Fundable Score – What Next?**
  If an application results in an award, the applicant will be working closely with the IC program officer on scientific and programmatic matters and a grants management officer on budgetary or administrative issues.

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

> ***The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.***

How do I get started?

You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:** https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated

by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement

4 Extension
5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution
8 Change of Institute or Division (noncompeting continuation)
9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR*, *NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008

(mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available. Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Teresa Lindquist, lindquit@niddk.nih.gov or 301-451-6418.

Grant Review-Related Policies

Foreign Organizations

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a significant foreign component.

Research Involving Human Subjects

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its scientific review groups (SRGs) and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations (Code of Federal Regulations, Title 45 Part 46).

There are several considerations for review of applications involving human subjects. These can be clustered into two broad areas: Protection of subjects from research risks; and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

SRGs assign inclusion codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below). The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections (OHRP) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL: http://grants.nih.gov/grants/peer/hs_review_inst.pdf.

Definitions:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information

derived from individually identifiable human subjects. A subset of research involving human subjects may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

Clinical research is defined as: (1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. (Excluded from the definition of patient-oriented research are in vitro studies that utilize human tissues that cannot be linked to a living individual.) Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; or (3) Outcomes research and health services research. http://www.nih.gov/news/crp/97report/execsum.htm

A Clinical Trial is operationally defined as a prospective biomedical or behavioral study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions.

An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

A ***valid analysis*** is required in phase III clinical trials. This means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis are:

- Allocation of study participants of both sexes/genders and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Research Conducted in a Foreign Country: For foreign awards, and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Children: For purposes of this policy, a child is an individual under the age of 21 years. This definition does not affect the human subject protection regulations for research on children (45 CFR 46) and their provisions for assent, permission, and consent, which remain unchanged. State laws define what constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

Exemption from Human Subjects Regulations

If the applicant designates an exemption from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, although reviewers need not evaluate questions related to research risks or the inclusion of women and minorities, the appropriate inclusion of children ***DOES*** need to be addressed for these applications.

Protection of Human Subjects

If the proposed research involves human subjects, and does not qualify as being exempt, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

- ***Risks to the subjects***
- ***Adequacy of protection against risks***
- ***Potential benefit of the proposed research to the subjects and others***.

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Women and Minorities in Study Populations

There are clear scientific and public health reasons for including women and minorities in study populations. Accordingly, the NIH requires that applications for clinical research give appropriate attention to including members of these groups in studies. If this is impossible (for example, because the disease occurs only in men or is prevalent only in one racial or ethnic group), or is inappropriate with respect to the health of the subjects, a strong scientific rationale or other well-supported justification is necessary. Unless the rationale/justification is compelling, NIH will not fund such applications. This policy covers research grants, cooperative agreements, and research contracts.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These inclusion codes, described below, appear on the summary statement.

Council will consider the degree to which the applicants have addressed this policy when it evaluates applications. Applications with inadequate representation of women and minorities and/or inadequate justification may be deferred, approved based on portfolio considerations, or approved with the condition that staff will ensure compliance with the policy before award. Council will be subsequently notified of awards for these types of approvals.

The NIH will not award research grants, cooperative agreements, or contracts to applicants who do not follow this policy.

Inclusion of Children as Participants in Research

To ensure that adequate data is developed to support the treatment of modalities for disorders and conditions that affect children, as well as adults, it is the policy of NIH that children (i.e., individuals 21 years of age and under) must be included in all human subjects research conducted or supported by the NIH. Children will not be excluded from this policy unless there are scientific and ethical reasons

not to include them in the research being conducted; well-supported justification for the exclusion will be necessary. This policy applies to all research involving human subjects, **including** research that is otherwise "exempt". Proposals for research involving human subjects **must** include a description of plans for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion.

The section in the application titled "Inclusion of Children" should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan **must** also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Specific exclusionary circumstances and other pertinent information on the inclusion of children in NIH-supported research may be found at: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Use of Human Embryonic Stem Cells in NIH-Supported Research

On August 9, 2001, at 9:00 p.m. EDT, President George W. Bush announced his decision to allow Federal funds to be used for research on existing human embryonic stem cell lines as long as prior to his announcement (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being. In addition, President Bush established the following criteria that must be met:

- The stem cells must have been derived from an embryo that was created for reproductive purposes;
- The embryo was no longer needed for these purposes;
- Informed consent must have been obtained for the donation of the embryo;
- No financial inducements were provided for donation of the embryo.

NIH's Role. In implementing this policy, NIH funds research scientists to conduct research on existing human embryonic stem cells and to explore the enormous promise of these unique cells, including their potential to produce breakthrough therapies and cures.

Investigators from 14 laboratories in the United States, India, Israel, Singapore, Sweden, and South Korea have derived stem cells from 71 individual, genetically diverse blastocysts. These derivations meet President Bush's criteria for use in federally funded human embryonic stem cell research. NIH has consulted with each of the investigators who have derived these cells. These scientists are working with the NIH and the research community to establish a research infrastructure to ensure the successful handling and the use of these cells in the laboratory.

In order to facilitate research using human embryonic stem cells, NIH created the Human Embryonic Stem Cell Registry, which lists the human embryonic stem cell lines—at varying stages of development—that meet the eligibility criteria. Entities that have developed stem cell lines that meet President Bush's criteria and are therefore eligible for Federal funding are listed at http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp.

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, scientific review groups, and Advisory Councils to share this responsibility and review research activities for compliance with the Public Health Service policy for the care and use of vertebrate animals. The general intent of the law and policy can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists;
- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain, or injury. Special attention must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Any comments or concerns that scientific review group members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; a "comment" is a scientific review group observation that will be communicated in the summary statement as a suggestion to the principal investigator. For projects involving animals, the species used is separately identified at the end of the “Description” in the summary statement. Any comments or concerns that members have regarding treatment and welfare of research animals used in the project are explained in a separate paragraph in the summary statement. Any questions Council members may have should be directed to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) staff.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns (*see I*nclusion Codes above).

No research involving animals may be conducted or supported by NIH until the institution proposing the research has provided a written assurance acceptable to NIH.

Inclusion Codes

Gender, Minority, and Children Codes

An NIH-Defined CLINICAL TRIAL? Y Or N

GENDER CODE	**MINORITY CODE**	**CHILDREN CODE**:
First character = G	*First character* = M	*First character* = C
Second character: 1 = Both Genders	*Second character*: 1 = Minority & Non-minority	*Second character*: 1 = Both children & adults
2 = Only Women	2 = Only Minority	2 = Only children
3 = Only Men	3 = Only Non-minority	3 = No children included
4 = Gender Unknown	4 = Minority Representation Unknown	4 = Representation of children unknown
Third character: A = Scientifically Acceptable U = Scientifically Unacceptable	*Third character*: A = Scientifically Acceptable U = Scientifically Unacceptable	*Third character*: A = Scientifically Acceptable U = Scientifically Unacceptable

Vertebrate Animal Codes

Code 10 No Live Vertebrate Animals Involved

Code 30 Live Vertebrate Animals Involved, no SRG Comments or Concerns
Code 44 Animals Involved - Certified - SRG Concerns
Code 45 Animals Involved - No Assurance - No SRG Comments or Concerns
Code 47 Animals Involved - No Assurance, SRG Comments
Code 49 Animals Involved - No Assurance, SRG Concerns

Biomedical Safety

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the scientific review group in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement. In the case of research involving human immunodeficiency virus, researchers are expected to follow the latest Centers for Disease Control and Prevention recommendations and guidelines for health care workers and laboratory personnel. In research involving recombinant DNA, assessment of an applicant's compliance with Public Health Service guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

Advisory Council Policy/Logistical Documents

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of Council must return the material given to them to the Executive Secretary at the conclusion of the meeting. All materials members have received at home or at their institutions also must be returned for disposition.
There should be no direct communication between members of Council and applicants. In addition to legal considerations, pre-mature notification of recommendations to applicants often leads to misinterpretation and distortion of discussions and recommendations.
As soon after the Council meeting as possible, applicants will be notified by NIDDK staff about the status of their applications.

Conflict of Interest

NIH takes extreme precautions to avoid placing Council members in situations where there might be an actual or apparent conflict of interest. Thus, at each Council meeting, procedures are delineated to avoid such conflicts.

A member must be absent from the meeting room during review of an application submitted by an institution, or a component of a system of institutions, in which the member or member's spouse, parent, child, partner, or close professional associate is an employee, or in which there is a directive or consultative relationship or financial interest. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

The NIH has been granted a regulatory waiver by the Office of Government Ethics so that faculty of multi-campus institutions of higher education who serve as experts or consultants to DHHS may participate in matters affecting one campus of a state multi-campus institution if the expert's disqualifying financial interest is employment with no multi-campus responsibilities at a separate campus.

Additionally, a Council member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, a recent collaborator, or a close personal friend. Further, a member should not take part in the discussion of an application from a scientist with whom the member has had long-standing differences which reasonably could be viewed as affecting the member's objectivity.

Council members present at each Council meeting sign a statement certifying that they did not participate in the discussion of, or vote on, any application from their own institution or an institution in which they have a financial interest.

Though the staff attempts to identify possible conflicts of interest and bring them to the attention of the Chairperson, the National Diabetes and Digestive and Kidney Diseases Advisory Council needs the assistance of members to ensure that such conflicts do not arise.

Lobbying

Technically, Council members are Government employees and governed by DHHS standards of conduct during the days they are being paid for duty. Thus, during the full midnight-to-midnight period of each of these days, members cannot transact personal business, enter into personal activities with the Legislative or Executive branches of Government, or discuss with NIH staff matters pertaining to their institution's federally funded activities. During this same period, members of Council also must not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Freedom of Information and Privacy Act

The Freedom of Information Act (FOIA) of 1967 and the Privacy Act of 1974 have significantly affected the NIH review and disclosure processes. Under FOIA, a person may obtain access to any Government record, including records about himself or herself, unless the records fall within one of nine exemptions to the Act. The Privacy Act, on the other hand, is limited to records about individuals which are maintained in a "system of records" from which information is retrieved by his or her name or other personal identifier.

For example, under FOIA, third parties may receive copies of awarded grant applications, but they may not received copies of applications that were scored but not funded or applications that were not recommended for further consideration. Also, under the Privacy Act, Principal Investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports and summary statements, but not individual reviews. Reviewers' written comments are not retained after their substance has been incorporated into summary statements or site visit reports.

The Freedom of Information and Privacy Acts

	FREEDOM OF INFORMATION REFORM ACT OF 1986 (P.L. 93-570)	**PRIVACY ACT OF 1974 (P.L. 93-579, DEC. 1974)**
PURPOSE	To allow access by the public to government records.	To provide safeguards for an individual against invasion of personal privacy.
SCOPE	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • methods whereby public may obtain records; • types of records available to the public; • exemptions that permit agencies to withhold certain types of records	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • any system of records from which information is retrieved by an individual's name, identifying number, or other identifying particular assigned to an individual; • any system of records maintained by a government contractor if the agency provides by contract for the "operation by or on behalf of the agency to accomplish an agency function."
REQUIREMENTS	Requires Federal agencies to: • publish in the Federal Register organizational descriptions and locations of agency records; • make all Agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying; • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting records; • make records promptly available to any person following the established guidelines for requesting such records; • make available for public inspection a record of the final votes of each member in every Agency proceeding, except as exempted; • release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletions of commercial information, information that would invade personal privacy, and internal government options and advice.	Requires Federal agencies to: • permit individuals to determine what records pertaining to them the agency collects, maintains, uses, or disseminates; • permit individuals to prevent records pertaining to them obtained for a particular purpose from being used or made available for another purpose without their consent; • permit individuals to gain access to information pertaining to them in agency records, to have a copy made of their records, and to correct or amend their records; • collect, maintain, use, or disseminate records of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of information; • be subject to civil or criminal sanctions as a result of willful or intentional actions which violate any individual's rights under the Act; • publish annually a notice in the Federal Register indicating the existence and character of the system records..
SUMMARY	Makes possible disclosure of policy, procedures, and records to the public.	Safeguards the privacy of individuals in the face of disclosure.

Travel Expenses and Reimbursement

Allowable consultant expenses for members of NDDKAC are round-trip transportation (from home to Bethesda, Maryland, and back), ground transportation (taxi fares, parking, tolls, etc.), hotel (Government room rate and associated taxes), and per diem costs. A consultant fee is paid to the Council member for each day or fraction of a day spent on official duty.

Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is $0.585 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently $64.00 per day for the Washington, D.C., metropolitan area. You will receive ¾ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. A consultant fee is paid to the Council member for each day or fraction of a day spent on official duty.

Travel Instructions

Omega World Travel will make a "Courtesy Reservation" and then it is the Council member's responsibility to contact Omega Travel at 1-800-253-1098 to confirm/change the travel reservation. All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. If not using Omega World Travel, travelers will be reimbursed for transportation after the Council meeting. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

Hotel Information

You will receive hotel reservation information prior to the meeting. It is necessary for Council members to call the hotel and reserve a room with their credit card. Ask for the block of rooms reserved for the NIH/NIDDK meeting. Also please confirm your check-in and check-out dates, especially if arriving late.

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include receipts for taxi fares, tolls, parking fees, the original airline ticket stub, plus the original hotel bill. Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days.

Travel Expense forms and receipts should be sent to:

Dora A. Abankwah, Assistant to Director
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 713A
6707 Democracy Boulevard
Bethesda, MD 20892-5452

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket $_____
- **Original Hotel** itemized receipt:
  - Room Rate $_____
  - Hotel Taxes $_____
  - Phone Calls ($5.00 per day are reimbursable) $_____
- Other travel-related receipts **over $75.00** $_____
- Rental car (reimbursement must be pre-approved) $_____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x 55 cents) $_____
- Parking Fees $_____
- Taxis:
  - From Residence to Terminal $_____
  - From Terminal to Hotel $_____
  - From NIH Campus to Terminal $_____
  - From Terminal to Residence $_____
  - Other $_____
- Tolls $_____
- Other miscellaneous expenses $_____

  (Please describe:_____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of $64.00 per day. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

SIGNATURE: _____

DATE: _____

NIDDK Advisory Council Orientation Reference Links
February 2009

General Background Information About the Council

- **Advisory Council Home Page on the Web**: http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/
- **Advisory Council Charter**: http://www2.niddk.nih.gov/NR/rdonlyres/DAE5E2F8-6380-45B7-BBFA-B42B94E06392/0/NIDDKCouncilCharter102008.PDF
- **Advisory Council Membership Roster**: http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/AdvisoryCouncilRoster.htm
- **Advisory Council Operating Procedures:** (being revised; available at orientation meeting)

General Background Information About NIDDK and Funding Policies

- **NIDDK Mission**: http://www.nih.gov/about/almanac/organization/NIDDK.htm
- **NIDDK Organization**: http://www2.niddk.nih.gov/AboutNIDDK/Organization/default.htm and http://www2.niddk.nih.gov/NR/rdonlyres/CAABE13F-C6B0-49F7-89B6-39D69F3FAF0A/9937/NIDDK_OrgChart.pdf
- **NIDDK Interim FY 2009 Funding Policy:** http://www2.niddk.nih.gov/Funding/Grants/FundingPolicy.htm

Administrative Matters Regarding Council Membership

- **Confidentiality and Conflict of Interest:**
  - **Confidentiality**: http://www2.niddk.nih.gov/NR/rdonlyres/0779AF27-CAF7-4D91-9D73-6246B26B50D4/0/AI12.pdf
  - **Conflict of Interest**: http://www2.niddk.nih.gov/NR/rdonlyres/670481DD-2214-411B-8AC3-380F17C5EB80/0/AI1.pdf
- **Lobbying:** http://www2.niddk.nih.gov/NR/rdonlyres/B527A179-CBF2-4813-A25D-EA152DD6169C/0/AI2.pdf
- **Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book:** http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/DEA/ReviewBranch/DEAReviewBranchBook
- **Travel Reimbursement:** (see Travel Expenses and Reimbursement and Sample Expense Form, in Background Information, Advisory Council Logistical Documents)

The Grant Process

- **NIH Dual Levels of Review:** http://www2.niddk.nih.gov/NR/rdonlyres/C2317A28-B024-4864-82C9-EAF83BCBBA55/0/dual_rev_system.pdf

- **NIH Funding Instruments:** http://www2.niddk.nih.gov/NR/rdonlyres/D67EEF97-C25F-4CB9-AA5F-1A039A009DDB/0/fund_instr.pdf

- **Funding Mechanisms (Activity Codes) Used by NIDDK:** http://www2.niddk.nih.gov/NR/rdonlyres/D03713D0-342C-4FDF-A53C-8214D9085724/0/actcodedef.pdf (2009 Orientation Handbook will have a slightly updated version of this document)

- **Review Process from Application to Award:** http://www2.niddk.nih.gov/NR/rdonlyres/965D13B7-5E71-4051-9D9F-C497C931F5A5/0/rev_pro_app_award.pdf

- **Peer Review Process Video:** http://cms.csr.nih.gov/ResourcesforApplicants/InsidetheNIHGrantReviewProcessVideo.htm

- **Peer Review Guidelines and Information:** http://www.csr.nih.gov/guidelines/proc.htm and http://enhancing-peer-review.nih.gov/background.html

- **Glossary of Terms Used in NIH Grant Process:** http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/Orientation/OrientationGlossary (being revised)

Grant Policies and Regulations

- **Freedom of Information Act & Privacy Act:** http://www2.niddk.nih.gov/NR/rdonlyres/E4CC0173-DBA2-4C4F-9A19-9202A5725173/0/AI10.pdf and http://www2.niddk.nih.gov/NR/rdonlyres/81998744-5A0D-43D1-BE25-ABE9C0C79823/0/AI102.pdf