Human Subjects Research: Experience in Developing Policies and Procedures at NIH

Carlos E. Caban, Ph.D., M.P.H.
NIH Extramural Program Policy Officer
Office of Extramural Research, NIH
cc25a@nih.gov
301 435-2690

Highlights

1. The NIH Mission & Budget
2. How NIH is organized and functions
3. Applying for funding; the PHS 398, Peer Review and Award
4. Human Subjects Research

1. NIH Mission

- The NIH mission is to uncover new knowledge that will lead to better health for everyone --
  - to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold.
- NIH is committed to the highest ethical and scientific standards for HS research

NIH Budget

- NIH Budget $28.59 Billion (FY 2004)
- ~82% is in Extramural Awards to the research community
- ~10% is for Intramural Research at NIH
- 15,174 Competing Awards (all types, FY2002)
- 55,046 awards total (all types, FY2002)
- ~30% Overall NIH Success Rate
- 30-35% Involve Human Subjects

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National Institutes of Health

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- Premature Infants' Deficits Persist Until Adulthood
- Panel Supports Therapeutic ERCP
- Learning Disabilities in Neurofibromatosis
- Moderately Premature Birth Poses Developmental Risks
- The SMART Way to Fight AIDS
- Stem Cell Information Index
- More...

Health Information
Publications & fact sheets, ClinicalTrials.gov, health hotlines, A-Z topic index, MEDLINEplus, other resources

Grants & Funding Opportunities
Grants news, Applications, grants policy, NIH Guide, award data, research training, research contracts, CRISP database

News & Events
In the News, press releases, calendars, radio & video, media contacts, special reports

Scientific Resources
Human Embryonic Stem Cell Registry, Intramural research, special interest groups, library catalogs, journals, training, labs, scientific computing

Institutes, Centers & Offices
The individual organizations that make up the NIH

About NIH
Visitor info, jobs, science education, employee directory, public involvement, policy issues, organization & mission, history, doing business with NIH, FOIA, Director's Page


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National Institutes of Health (NIH)
Bethesda, Maryland 20892

Department of Health and Human Services

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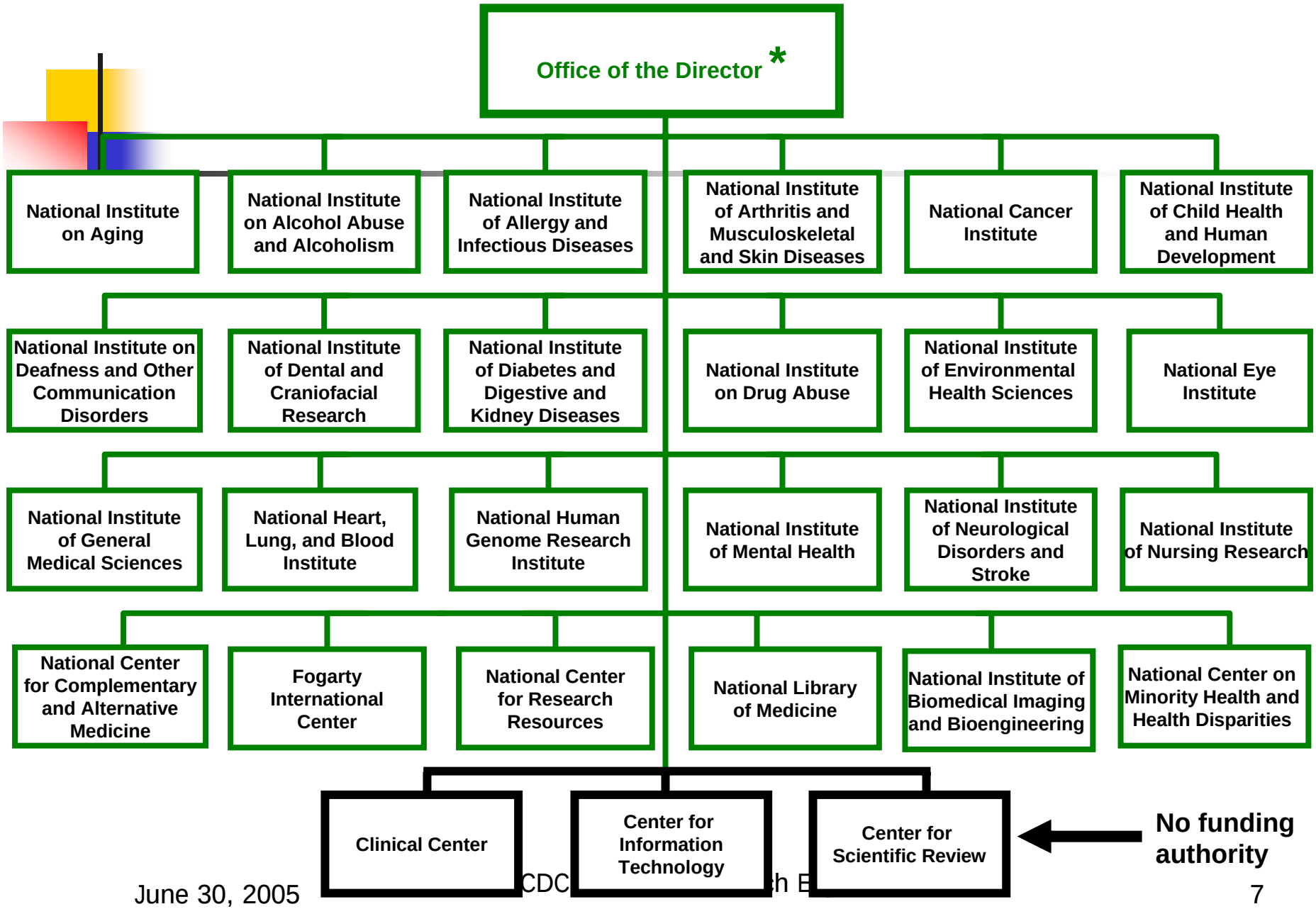
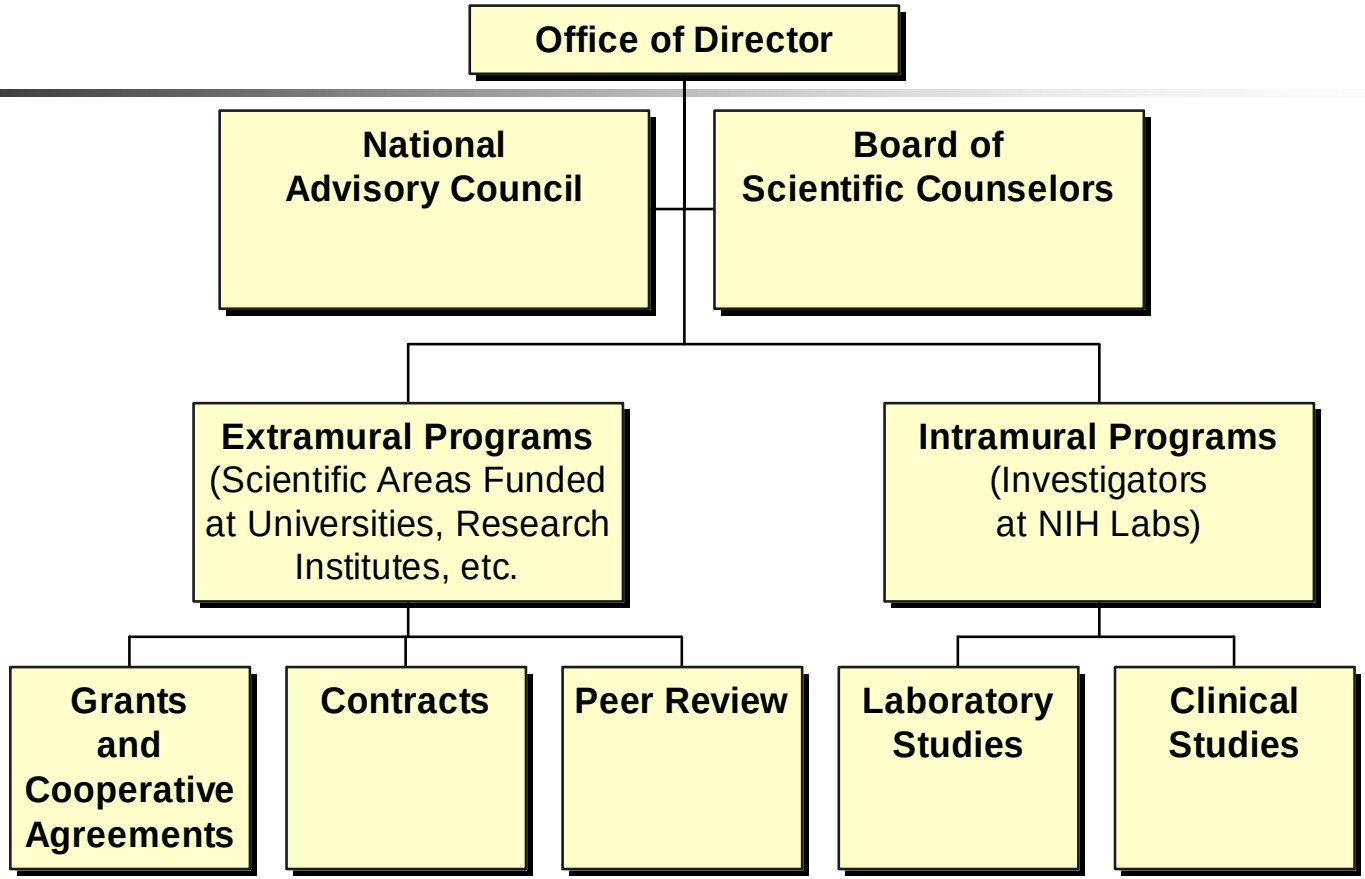
2. NIH Organization

- 27 Institutes and Centers (ICs)
  - 24 ICs Provide Separate Funding for Research Projects and Activities
- Office of Director
  - Office of Extramural Research(OER)
  - Office of Intramural Research (OIR)
  - OD Offices for Trans-NIH Initiatives
  - ORWH; OBSSR: ODP; OAR;OC;


Office of the Director *
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Cancer Institute
National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders
National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Drug Abuse
National Institute of Environmental Health Sciences
National Eye Institute
National Institute of General Medical Sciences
National Heart, Lung, and Blood Institute
National Human Genome Research Institute
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Center for Complementary and Alternative Medicine
Fogarty International Center
National Center for Research Resources
National Library of Medicine
National Institute of Biomedical Imaging and Bioengineering
National Center on Minority Health and Health Disparities
Clinical Center
Center for Information Technology
Center for Scientific Review
No funding authority

Institute Organizational Chart Model



OD Level NIH Extramural vs Intramural Research

At the OD level:

NIH Extramural Research (DDER)

- is administratively separate
- and financially separate
- and has separate peer review process

from NIH Intramural Research(DDIR)

Office of Extramural Research (Deputy Director for Extramural Research)

- Office of Extramural Programs(OEP)
- Office of Policy for Extramural Research Administration (OPERA)
- Office of Extramural Reports Research Management (OERRM)
- Office of Laboratory Animal Welfare
- Office of Administrative Operations

Office of Extramural Programs (JoAnne Goodnight, Acting Director)

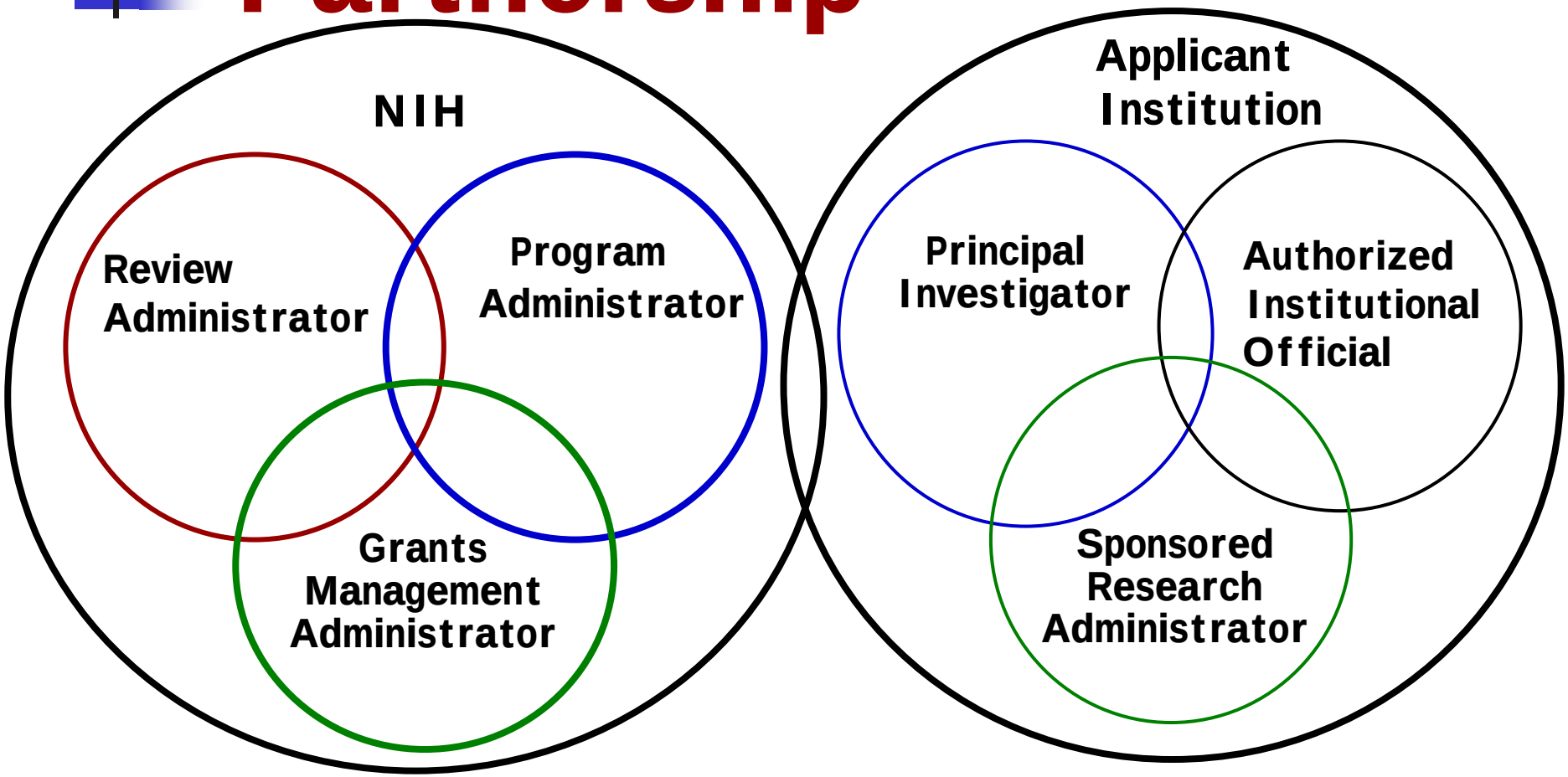
Develops and Implements Trans-NIH Extramural Program Policies

- Extramural Program Policy Officer (Caban)
- Extramural Human Subects Research Policy Officer (Gordon)
- Extramural Research Integrity Officer (Gordon)
- Review Policy Officer (Coelho)
- Research Training Officer (Goldschmidts)
- SBIR/STTR Coordinator (Goodnight)
- Extramural Staff Training Officer (Selden)
- NIH GUIDE (Paddock; Grove)

NIH Has Separation of Peer Review from Program Management

- Center for Scientific Review (CSR) is independent of the Institutes/Centers
  - receives applications
  - reviews majority of Grants
- Each Institute/Center has a separate Review Office in addition to CSR
- Program management is in each I/C

The Research Partnership



NIH GUIDE on WWW

http://grants.nih.gov/grants/guide/index.html

- NOTICES
  - Policies, Workshops, & Other Information
  - RFPs - Requests for contract proposals
- REQUESTS FOR APPLICATIONS(RFA)
  - Highest Priority Research Topic - $ Attached
  - Special Receipt Date - Special Review Cmt
- PROGRAM ANNOUNCEMENT (PA)
  - High Priority Research Area - No $ Attached
  - Regular Receipt Dates - CSR Review Cmts

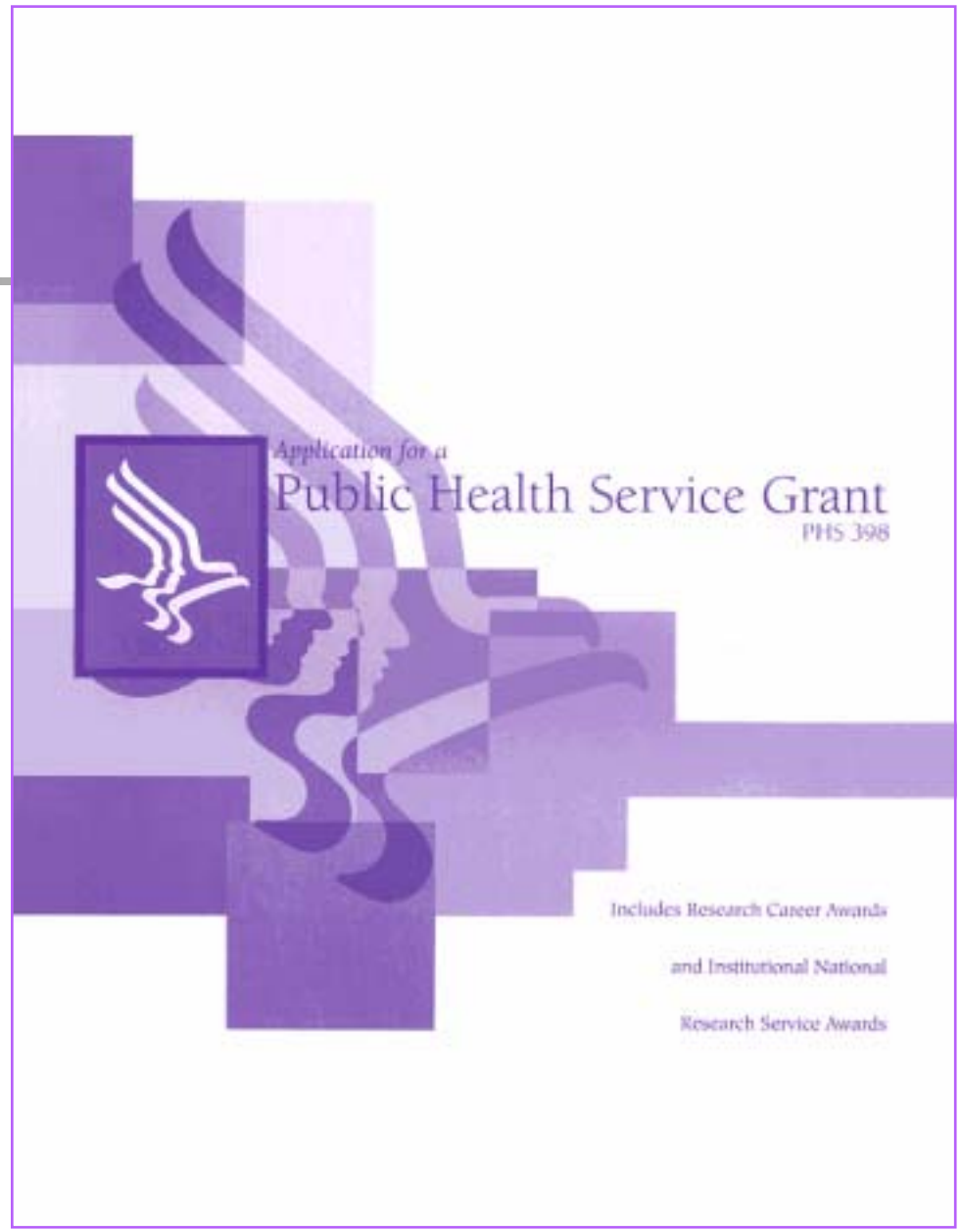
Office of Extramural Research(OER) Website: http://grants.nih.gov/grants/oer.htm

- **NIH Funding Opportunities**
  - **NIH GUIDE for Grants**
  - **NIH Research Training Opportunities**
    - Extramural Programs
    - Intramural Res/Tr Opportunities
    - Training Q&A and FAQs
  - **SBIR/STTR**
  - **NIH Roadmap Initiatives**
- **Grant Application Submission**
  - **NIH Forms and Applications**
  - **Investigator/Grantee Resources**
- **Awarded Grants Information**
  - **Award Data**
  - **CRISP Database of Awarded Grants**

- **Grants Policy and Guidelines**
  - Grants Policy & Guidance
  - Selected Grant Programs
  - Edison: Invention
  - Laboratory Animal Welfare
  - Human Subjects
  - Peer Review Policy & Issues
    - Reviewers Instructions
- **Electronic Research Administration (eRA)**
  - **eRA Home Page**
  - **NIH Commons**
  - **iEdison: Invention Reporting**
- **About OER- OER Resources**
  - **Introduction to Extramural Research**
  - **OER Outreach Activities**
  - **OER Help and Other Resources**
    - **Getting Help from OER**
    - **Staff Directories**
    - **Etc.**

PHS Research Grant Application Kit (form PHS 398)

Electronic Forms and Instructions



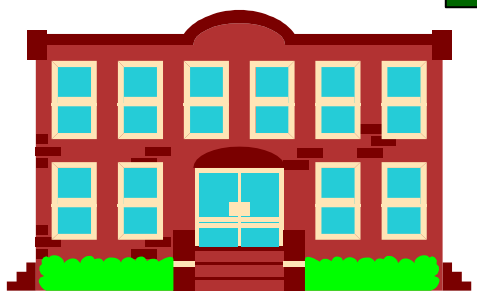
REVIEW PROCESS FOR NIH RESEARCH GRANTS

Research Grant Application (PI)

School or Other Research Center (Applicant)

Principal Investigator Initiates Research Idea

Submits application



National Institutes of Health

Center for Scientific Review

Assign to IC and SRG

Scientific Review Group

Review for Scientific Merit

Institute

Evaluate for Relevance

Advisory Council or Board

Recommends Action

Institute Director

Takes final action for NIH Director

Allocates Funds $$

Conducts Research

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 Recommends for Level of Support and Duration of Award

Second Level of Review

Advisory Council

Assesses Quality of SRG Review of Grant Applications

Makes Recommendation to Institute Staff on Funding

Evaluates Program Priorities and Relevance

TYPES OF REVIEW COMMITTEES:

Chartered Study Sections

- when the subject matter of the application matches the referral guidelines for the standing study section

Special Emphasis Panels (SEPs)

- when the subject matter does not fit into any study section, or
- when assignment of an application to the most appropriate study section would create a conflict of interest, or
- Special Mechanisms (RFA, Fellowships, SBIRs, AREAS, etc.)

Scientific Review Group or Study Section Actions

- Scored, Scientific Merit Rating (includes HS & AW)
- Priority scores:

  1 (best) to 5 (poorest) and percentiles
- Unscored (lower half)
- Deferral

Summary Statement

After the review meeting is finished, the results are documented by the SRA in a summary statement and forwarded to the PI and to the assigned NIH Institute. The assigned NIH Institute is responsible for making a funding decision.

The summary statement contains:

- Overall Resume and Summary of Review Discussion
- Essentially Unedited Critiques of Assigned Reviewer
- Priority Score and Percentile Ranking
- Budget Recommendations
- Administrative Notes

Just-In-Time Information

- NIH Policy allows submission of certain data elements to be deferred; e.g., not at time of the initial application. Information is requested later, for those grants in a certain priority score range.
- Data elements includes:
  - IACUC Approval Date (within 3 yrs)
  - IRB Approval Date (within 1 yr)
  - Certification of Education on Human Subjects
  - Other Support of Key Personnel

PostAward: Non-Competing Continuation Progress Reports

- An annual progress report is due two months prior to anniversary date
- Use the PHS2590 instructions and form pages found at:

  http://grants.nih.gov/grants/funding/2590/2590.htm
- SNAP and Non-SNAP processes are detailed in the instructions

Electronic Research Administration

- Federal Government initiative to do business electronically
- NIH is part of the e-grants initiative
- NIH Commons
  - Institution registers in the commons
  - Institution identifies their PIs, who register
  - PI/Institution has access to its information and can submit grants (2005) and progress reports (via eSNAP since 2003) electronically
  - PI can check on grant status and summary statement

NIH eRA/IMPAC II Systems: Commons registration and use Statistics 10/12/2004

PART OF THE Federal E-GRANT Initiative

- Registered Organizations: 1,801
- Registered Persons = 25,958
- Registered PIs = 19,902
- Commons Logons Since October 2002 (internal and external) = 663,398
- Financial Status Reports (FSR): 42,199 processed
- eSNAP (2590 Progress Reports): 2,976 submitted
- Extensions Without Additional Cost = 2,981
- Just in Time Documents submitted = 602

Non-Competing Continuation Progress Reports - NIH Commons

- Commons-registered institutions and PIs
  - Have access to due date information through the Commons Status system
  - Have access to pre-populated face pages via Status
  - eRA Commons Website: https://commons.era.nih.gov/commons/index.jsp

Human Subjects Research

Outline

- HHS Regulations: 45 CFR part 46

  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
- Definitions
- NIH Policies: Human Subjects/Clinical Research
- Applying for NIH funding for research involving human subjects
- Resources

HHS Regulations

- 45 CFR part 46 – Protection of Human Research Subjects
  - **Subpart A**--Federal Policy for the Protection of Human Subjects
  - **Subpart B** --Additional Protections for Pregnant Women, Human Fetuses and Neonates
  - **Subpart C** --Additional Protections for Prisoners
  - **Subpart D** --Additional Protections for Children in Research

What is *risk*?

... the probability of

- harm

or

- discomfort

Extracted from:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

Definition of *research*

- ... a systematic investigation
  - research development
  - testing, and
  - evaluation
- designed to develop or contribute to generalizable knowledge

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

Definition of *human subject*

- ... a living individual
- about whom an investigator... conducting research obtains

1) Data through intervention or interaction with the individual,

or

2) Identifiable private information

Definition of *investigator*

- Includes anyone involved in conducting the research

  Individuals/Repositories that:

  - Provide coded human data or specimens and collaborate on other activities related to conducting the research are involved in HS research
  - Solely provide previously-collected coded human data or specimens are not involved in HS research

  http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

OHRP Responsibilities

- Office for Human Research Protections (OHRP) is in Office of the Assistant Secretary for Health, DHHS

http://ohrp.osophs.dhhs.gov/index.html

- **OHRP is responsible for**:
  - Issuing **Assurances** to institutions "engaged" in federally-funded human research and **registering IRBs** which provide approval and oversight for human subjects research

    http://ohrp.osophs.dhhs.gov/irbasur.htm
  - Developing and updating policy and guidance documents
  - Education
  - Compliance with HHS Human Subjects Protections Regulations

    http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

NIH Responsibilities

NIH assesses proposed research for protections against research risk:

- **Consistency with HHS Regulations**
  - **Subpart A** - Federal Policy for the Protection of Human Subjects
  - **Subpart B** – Additional Protections for Pregnant Women, Human Fetuses and Neonates
  - **Subpart C** – Additional Protections for Prisoners
    http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm
  - **Subpart D** – Additional Protections for Children
- **Compliance with NIH Policies and Guidance**
  - Data and Safety Monitoring Plans for Clinical Trials
  - Required Education for Protection of Human Subjects in Research

NIH Requirements

- NIH Policies
  - **Human Research Protections**
    - Data and Safety Monitoring
    - Human Subjects Education
  - **Clinical Research**
    - Inclusion of Women and Minorities
    - Inclusion of Children
    - Valid Analyses for NIH-defined Phase III Clinical Trials

HHS Regulations: NIH v. IRB Responsibilities

- NIH Responsibilities
  - Evaluation of proposed research involving human subjects for protections
    - Delegated to peer review process and NIH staff
  - “On the basis of this evaluation [NIH] may approve or disapprove the application ... or enter into negotiations to develop an approvable one.”
  - “Federal funds... may not be expended for research involving human subjects unless the requirements... have been satisfied.”

    (46.120 &122)

HHS Regulations: NIH v. IRB Responsibilities

- IRB Responsibilities
  - Initial and continuing review of research involving human subjects
  - To “approve, require modifications in..., or disapprove research” (46.108)
    - Ensure rights & welfare of human subjects
    - Protection of institution

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY.		
Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR	New Investigator ☐ No ☐ Yes	
3a. NAME (Last, first, middle)	3b. DEGREE(S)	3h. eRA Commons User Name
3c. POSITION TITLE	3d. MAILING ADDRESS *(Street, city, state, zip code)*	
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3f. MAJOR SUBDIVISION		
3g. TELEPHONE AND FAX *(Area code, number and extension)* TEL: FAX:	E-MAIL ADDRESS:	

4. HUMAN SUBJECTS RESEARCH No ☐ Yes ☐	4b. Human Subjects Assurance No.		5. VERTEBRATE ANIMALS ☐ No ☐ Yes	
	4c. Clinical Trial ☐ No ☐ Yes	4d. NIH-defined Phase III Clinical Trial ☐ No ☐ Yes	5a. If "Yes," IACUC approval Date	5b. Animal welfare assurance no.
4a. Research Exempt No ☐ Yes ☐	If "Yes," Exemption No.			

6. DATES OF PROPOSED PERIOD OF	7. COSTS REQUESTED FOR INITIAL	8. COSTS REQUESTED FOR PROPOSED

Application (PHS 398): Human Subjects Research

- PI should enter YES in Item 4 on application facepage;
- **Exemptions** designated in Item 4a often represent the opinion of the PI because
  - OHRP Guidance states Exemptions should be independently determined;

    http://ohrp.osophs.dhhs.gov/humansubjects/guidance/wirbproc.pdf
  - Institutions often designate IRB to make determination; and
  - NIH does not require IRB approval until prior to award
- Required information must appear in the Research Plan in **Section e. Human Subjects**

PHS 398 Part II: Instructions for Preparing the Human Subjects Section

- All proposed research will fall into one of six scenarios:
  - **A**: No Human Subjects
  - **B**: Human Subjects Research, Exemption 4
  - **C**: Human Subjects Research, Exemptions 1,2,3,5,6
  - **D**: Clinical Research
  - **E**: Clinical Trial(s)
  - **F**: NIH-defined Phase III Clinical Trial(s)

Which scenario matches?

- **Questions to assist in identifying correct scenario:**

1. Human Subjects?
2. Exempt Human Subjects research?
3. Clinical Research?
4. Clinical Trial?
5. NIH-defined Phase III Clinical Trial?

Question 1: Human Subjects Research?

- **PHS 398 Item 4:** Yes
- Human Subjects Research
- Research Plan Section E. Human Subjects:
  - Risks
  - Adequacy of protections against risks
  - Potential benefits
  - Importance of knowledge to be gained

http://grants.nih.gov/grants/funding/phs398/instructions2/phs398instructions.htm

NIH Human Subjects Education Requirement

- Before award, provide documentation that Key Personnel have been trained in the protection of human subjects.
  - Key Personnel: involved in design &/or conduct of research involving human subjects
  - Training is determined by institution

http://grants.nih.gov/grants/policy/hs_educ_faq.htm

Certification of IRB Review and Approval

- Certification of IRB review and approval (includes all participating sites)

  [45CFR46103(b)]

- Just-In-Time submission to NIH
  - IRB approval is not required until prior to award

  http://grants.nih.gov/grants/policy/policy.htm

Exempt Human Subjects Research

Involvement of human subjects limited to:

1. Educational strategies in educational settings
2. Interviews, surveys, etc. posing no risks (not involving children)
3. Same as above, but involving public officials
4. Existing data or specimens: publicly available or unidentifiable
5. Research on public benefit or service programs approved by Department or Agencies
6. Taste and food evaluation with ingredients having FDA, EPA, and USDA approval

Question 2: Exempt Human Subjects Research?

- **Exempt** Human Subjects Research
  - Exemption Category
  - Justification for exempt status
  - Population sample
    - Number
    - Age range
    - Health status
  - Sources of research materials or data

Determination of Exempt Human Subjects Research

- Investigators should not determine that research involving human subjects is exempt
  - OHRP guidance: Exemptions should be **independently determined** (http://www.hhs.gov/ohrp/humansubjects/guidance/irb71102.pdf).
- Institutions often designate IRB to make determination
- NIH Policy: Certification of IRB approval is Just-in-Time

Scientific Review of Human Research Protections

- Reviewers evaluate required information
  - "Acceptable" or "Unacceptable"
- Human Subjects Concern
  - Unacceptable risk or inadequate protection against risk to human subjects
    - Summary Statement:
      - **PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE**

Resolution of HS Concerns

- Peer Review determines HS =Unacceptable
- HS code = 44 = bar to award
- Only OEP can change HS code 44
- Requires appropriate information from PI, co-signed by Institutional Official
- Program Official approves and sends to OEP
- OEP concurs and changes code to 54 = resolved

Common Concerns (FY2004)

- Inadequate Human Subjects section (28%)
- Risks (22%)
- Issues related to Informed Consent (16%)
- Issues related to Confidentiality (12%)
- Missing/inadequate Data and Safety Monitoring (11%)
- Inequitable recruitment (7%)
- Other (4%)

Purpose of "OHRP Guidance on Research Involving Human Data or Specimens"

- Directed toward IRBs, investigators, and funding agencies
- Provides clarification of terms in HHS regulations
- http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
- Describes when research with coded data or specimens is not human subjects research
- Indicates that coded data/specimens that are designated "not human subjects" may still be covered by HIPAA, so protection against disclosure of identifiable private information may be protected
- Effective date: August 10, 2004

Definition of *Obtain*

- To receive or access individually identifiable human data or specimens
  - Includes an investigator's use, study, or analysis of human data or specimens already in investigator's possession

Definition of *Investigator*

- Includes anyone involved in conducting the research

  Individuals/Repositories that:

  - Provide coded human data or specimens and collaborate on other activities related to conducting the research are involved in HS research
  - Solely provide previously-collected coded human data or specimens are not involved in HS research

Definition of *Coded*

- Identifying information that enables the investigator to readily ascertain the identity of the individual has been replaced with a
  - number,
  - symbol, and/or
  - letter; **and**
- A key to the code exists, enabling linkage of information to an individual

Specific Information in Guidance

- Research with coded human data/specimens does not involve HS if:
  - Data/specimens not collected specifically for proposed study; and
  - PI(s) cannot readily ascertain identities of donors because:
    - Key to code destroyed before research begins; or
    - Non-disclosure agreement between provider and investigator (no requirement for IRB approval); or
    - IRB policies prohibit release of key to code; or
    - "Other legal requirements" prohibit release of key to code

Coded Data/Specimens Summary

- In order to determine whether research with coded data/specimens is human subjects research, you must determine:
  - Role of data/specimen provider
  - Role of recipient
  - What is being *obtained*

FAQs: Human Subjects Research?

- **Research involving "Focus Groups"**
  - **NO**, if research will involve consultants chosen for their expertise to improve research design
  - **NO**, if research will involve individuals recruited to test a new product/survey instrument in order to identify problems (β–testing)
  - **YES**, if research will involve small group representing target population and individually-identifiable information will be obtained, that could result in risks (pilot testing)

Question 3: Clinical Research?

- **Patient-oriented research**
- **Epidemiologic and behavioral studies**
- **Outcomes research and health services research**
  - Includes all Human Subjects Research except Exemption 4 research

Inclusion of Women/Minorities in Clinical Research

- Each study must have plans for:
  - Distribution by ethnicity/race; and
  - Distribution by sex/gender
  - Rationale for Exclusions
  - Outreach

HHS Regulations: Definition of *Children*

- ***Children***: individuals under legal age for consent to treatments or research procedures location where studies will be conducted (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.402)
  - Vulnerable population requiring protections in addition to those required for adults

    (Subpart D, 45CFR46)
    - Permission from parent/guardian
    - Assent from children (if they are capable and it is appropriate)

NIH Policy: Inclusion of Children

- "Children (i.e., individuals under the age of 21) must be included in research, ... unless there are scientific and ethical reasons not to include them."
- Research plan
  - "description of plans to include children ..., or explanation of the reason(s) for excluding children as participants in the research"

(http://grants1.nih.gov/grants/guide/notice-files/not98-024.html)

Scientific Review of Inclusion Plans

Scientific Reviewers will evaluate:

- **Inclusion** -
  - If proposed inclusion is appropriate for scientific objectives
  - Rationale for selection of subjects and composition of study population
- **Exclusion** -
  - Justification for exclusion when representation is limited or absent
    - Based on risks to health of participants &/or inclusion inappropriate with respect to the research topic
- **Assessment:** “Acceptable” or “Unacceptable”

Question 4: Clinical Trial?

- Prospective study to answer specific questions about biomedical or behavioral interventions

- Provide: Data and Safety Monitoring Plan
  - Required for all Clinical Trials
  - General Description in Grant Applications
    - Monitoring Entity
    - Process for Adverse Event Reporting

Before Award

Before award NIH staff require:

- OHRP Assurance Number for grantee institution
- Certification of IRB review and approval from IRB registered under grantee's Assurance number
- Acceptable/Resolved Human Subjects Protections
- Certification of Human Subjects Education for Key Personnel
- Acceptable/Resolved Inclusion of Women/Minorities/Children
- Plans for Valid Analyses for NIH-defined Phase III Clinical Trials

After Award

Human Protections Issues:

- Annual Progress reports from the grantee to the NIH and certification of continuing IRB review for non-exempt research
- Adverse Event Reports

Inclusion Issues:

- Inclusion Enrollment Tables
  - Part A: All Human Subjects
  - Part B: Hispanics and Latinos
- Separate tables for each study
- Separate tables for domestic and foreign populations

Resources/Links

- NIH Grants Policy Statement (12/03): http://grants.nih.gov/grants/policy/nihgps_2003/index.htm
- NIH Guide: http://grants.nih.gov/grants/guide/index.html
- PHS 398 Application (form pgs are PDF-fillable): http://grants1.nih.gov/grants/funding/phs398/phs398.html
- PHS2590 Progress Report (form pgs are PDF-fillable): http://grants.nih.gov/grants/funding/2590/2590.htm
- Office of Extramural Research Grants Home Page: http://grants.nih.gov/grants/oer.htm

Questions?