Special Administrative Issues

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. 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.

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.

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.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These codes, described below, appear on the summary statement.

Use of Human Embryonic Stem Cells In NIH Supported Intramural and Extramural Research

On August 9, 2001, at 9:00 p.m. EDT, the President 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, the President 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.

In order to facilitate research using human embryonic stem cells, the NIH is creating a Human Embryonic Stem Cell Registry that will list 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 the President's criteria and are therefore eligible for federal funding are listed at the following location: **http://escr.nih.gov**.
Information specific to NIDDK's programs is available at: http://www.niddk.nih.gov/fund/HESC_guide.htm

Inclusion of Children in Research (Effective October 1, 1998)

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. The National Institutes of Health Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects URL address is: **http://grants.nih.gov/grants/guide/notice-files/not98-024.html**

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 SRGs and Advisory Councils to evaluate all applications and proposals involving human subjects for compliance with human subject regulations (Code of Federal Regulations, Title 45 Part 46).

The 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.

SRGs assign the following codes to applications to indicate their judgment as to compliance with these concerns (codes appear on the summary statement):

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. The URL address is: **http://ohrp.osophs.dhhs.gov/**

No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

HUMAN SUBJECT CODES

Code 10	No Human Subjects Involved	
	Code 30	Human Subjects Involved, no SRG Comments or Concerns
	Code 44	Human Subjects Involved - Certified - SRG Concerns
	Code 45	Human Subjects Involved - No Assurance - No SRG Comments or Concerns
	Code 47	Human Subjects Involved - No Assurance, SRG Comments
	Code 49	Human Subjects Involved - No Assurance, SRG Concerns

Inclusion of Women, Minorities, and Children in Clinical Research
(Revised codes Effective October 1998)

All biomedical or behavioral research involving human subjects is considered clinical research. Only research projects that meet the NIH definition for Phase III Clinical Trials are coded as Clinical Trials. Only scored applications are assigned codes. All projects/subprojects are individually coded and an overall set of codes assigned to the application. Each project receives Gender, Minority, and Children 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:	*Second character*:	*Second character*:
1 = Both Genders	1 = Minority & Non-minority	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:	*Third character*:	*Third character*:
A = Scientifically Acceptable	A = Scientifically Acceptable	A = Scientifically Acceptable
U = Scientifically Unacceptable	U = Scientifically Unacceptable	U = Scientifically Unacceptable

Animal Welfare

Although the recipient institution and investigator bear the major responsibility for proper care and use of animals, NIH relies on its staff, SRGs, and Advisory Councils to review research activities for compliance with the PHS policy for the care and use of vertebrate animals. Care and use of vertebrate animals in funded projects must conform to applicable law and policy. 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 not be confined, restrained, transported, cared for, or used in experimental procedures in a manner to inflict any unnecessary discomfort, pain, or injury.

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.

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.

SRGs assign the following codes to applications to indicate their judgment as to compliance with these concerns (codes appear on the summary statement):

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

As with research involving human subjects, reviewers are expected to apply the collective standards of their professions in identifying potential hazards such as inappropriate handling of chemical carcinogens, infectious agents, and radioactive or explosive material. If applications pose special hazards, these hazards will be identified, and any concerns about the adequacy of safety procedures will be high-lighted in the summary statement "Critique section(s)."

No award will be made until all concerns about the hazardous conditions have been resolved to the satisfaction of the NIH.

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 PHS guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

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.