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Ethical and Safe Conduct in Science and Organizational Operations

NIH grants are subject to requirements intended to ensure that recipient organizations are responsible in their handling of Federal awards. Grantees are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, their employees, and organizations and individuals with whom they may collaborate, and that limit the potential for research results to be tainted by possible personal financial or other gain.

In addition, NIH grantees are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

Standards of Conduct

Grantees must establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a grantee to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities, and favors, nepotism, and such other areas as political participation and bribery. The standards also must:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper;
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official;
- Include a process for notification and review by the responsible official of potential or actual violations of the standards; and
- Specify the nature of penalties that the grantee may impose. These penalties would be in addition to any penalties that may be imposed by NIH or a cognizant Federal agency for infractions that also violate the terms or conditions of award.

The grantee is not required to submit its general standards of conduct to NIH for review or approval; however, a copy must be made available to each officer of the grantee, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The grantee is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and informing the IC Chief Grants Management Officer (CGMO) if the infraction is related to an NIH award. If a suspension or separation action is taken by a grantee against a PI or other key personnel under an NIH grant, the designated GMO must be notified as specified in “Administrative Requirements—Changes in Project and Budget.”

Financial Conflict of Interest

NIH also requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." That subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. These requirements do not apply to Phase I of the SBIR/STTR programs.

The signature of the authorized organizational official on the face page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F, including that:

- There is in effect, at that organization, a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought;
- Prior to the expenditure of any NIH funds awarded under a new award, the organization will inform the CGMO the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 identified by the organization;
- When informing the CGMO that a financial conflict of interest has been identified, the organization will assure that the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated;
- The organization will continue to make similar reports on subsequently identified conflicts; and
- The organization will make additional information available to NIH, upon request, as to how identified conflicting interests have been handled in accordance with the regulations.

As described in the regulations, examples of how financial conflicts of interest might be addressed include the following:

- Public disclosure of significant financial interests;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded by PHS;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.

Grantees also must ensure that consortium agreements address whether the consortium participant's employees will be subject to the financial conflict of interest requirements of the collaborating organization or to those of the grantee (see "Consortium Agreements").

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing, and reporting data. Although there is no regulatory requirement for Institutional Review Boards (IRBs) to consider investigator financial conflict of interest, in some cases IRBs are incorporating conflict of interest issues in their deliberations (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects.")

Some strategies used by IRBs to consider investigator conflict of interest include the following:

- Make IRBs aware of the organization's conflict of interest policies and procedures and elect to include a statement in the informed consent form that all clinical investigators comply with the organizational guidelines.

- Ask investigators to complete a short questionnaire in which they are asked whether they or any person responsible for the design, conduct, or reporting of research have an economic interest in, or acts as an officer or a director of any outside entity whose financial interest could reasonably appear to be affected by, the research.

- Provide instruction to IRB members during their orientation on how to identify and respond to a perceived financial, academic, or other conflict of interest.

Debarment and Suspension

HHS regulations published at 45 CFR Part 76 implement the government-wide debarment and suspension system for HHS' non-procurement transactions. "Nonprocurement transactions" include grants, cooperative agreements, scholarships, fellowships, and loans. Accordingly, applicants for NIH grants ("primary covered transactions"), including applicants for individual National Research Service Awards (fellowships), are required to certify[6] that, to the best of their knowledge and belief, they and their principals (including PIs and other key personnel):

- Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

- Have not, within the 3-year period preceding the application, been convicted of, or had a civil judgment rendered against them for, commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; for violation of a Federal or State antitrust statute; for commission of embezzlement, theft, forgery, bribery, falsification or destruction of records; or for making false statements or receiving stolen property;

[6] This certification is accomplished by the signature of the authorized organizational official on the application. States need only certify as to their principals.

- Are not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated above; and

- Have not, within a 3-year period preceding the application, had any public transaction (Federal, State, or local) terminated for cause or default.

If the applicant is unable to certify to these statements, it must, nonetheless, submit the certification and attach an explanation. The inability to certify does not automatically disqualify an organization from receiving an NIH award; however, failure to submit the required certification or the necessary explanation will cause NIH not to make an award. The full text of the instructions and the certification are included in Appendix A to 45 CFR Part 76.

A variety of "lower-tier" transactions also are subject to the certification requirement. Contractors under grants (where the contract requires the provision of goods or services that will equal or exceed $100,000) and all consortium participants must certify that they are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal agency. Grantees also are required to obtain a certification from each trainee under an institutional National Research Service Award prior to appointment. If an entity or individual is unable to certify to this effect, an explanation should be attached to its proposal or to the document that defines the legal relationship between the parties (for example, the consortium agreement).

Regardless of whether a certification is required or made, organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants or be paid from NIH grant funds, whether under a primary or lower-tier transaction, during the period of suspension, debarment, or exclusion.

Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the authorized organizational official agrees that the grantee will provide a drug-free workplace and will comply with requirements to notify NIH in the event that an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. HHS implementing regulations are set forth in 45 CFR Part 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)."

Health and Safety Guidelines

Grantees are responsible for meeting Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. The following standards and guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities, and they serve to supplement prevailing Federal, State, and local laws and regulations:

Smoke-Free Workplace

NIH strongly encourages all recipients of its grants to provide smoke-free workplaces and promote the nonuse of tobacco products. NIH defines the term "workplace" to mean office space (including private offices and other work space), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services

Ban on Human Embryo Research and Cloning

NIH appropriated funds may not be used to support human embryo research under any extramural award instrument. NIH funds may not be used for the creation of a human embryo(s) for research purposes or for research in which a human embryo(s) is destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 CFR 46.208(a)(2) and subsection 498 (a) and (b) of the PHS Act. The term "human embryo(s)" includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition to the statutory restrictions on human fetal research under subsections 498 (a) and (b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

Research on Human Fetal Tissue

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definitions does not include established human fetal cell lines.

NIH Guidance for Research on Human Fetal Tissue

NIH has issued guidance for grantees conducting research on human fetal tissue. The guidance and other information on the governing federal statute, Sections 498A and 498B of the Public Health Service Act, 42 USC 289g-1 and 298g-2, are available on the NIH web site at http://grants.nih.gov/grants/guide/notice-files/not93-235.html
The scientific and ethical challenges associated with research utilizing human fetal tissues make it imperative that researchers and their institutions be clearly aware of and in compliance with the federal requirements particularly section 498B. Violation of this statute carries criminal penalties that are applicable to both the suppliers and the acquirers of human fetal tissue for valuable consideration.

When an application involving human fetal tissue research is submitted to the NIH, the authorized institutional official certifies (by signing the face page) that researchers using these tissues are in compliance with Sec 498B of the Public Health Service Act, 42 U.S.C. 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to

profit, and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control or transportation of these tissues.

There are additional legal requirements for research on the transplantation of human fetal tissue for therapeutic purposes that is conducted or supported by the NIH. (See Sec 498A and Sec 498B(b) of the Public Health Service Act.) Under section 498A the institutional official who signs the application must certify that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the tissue is being donated for therapeutic transplantation research, that the donation is being made without any restriction regarding the identity of individuals who may receive the transplantation, and that the donation is being made without the donor knowing the identity of the recipient.

- The attending physician must sign a statement that the tissue has been obtained in accordance with the donor's signed statement and that full disclosure has been provided to the donor with regard to the physician's intent, if any, in the research to be conducted with the tissue, and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks of the type that are associated with the woman's medical care. In the case of tissue obtained pursuant to an induced abortion, the physician's statement must also state that the woman's consent for the abortion was obtained prior to requesting or obtaining consent for the tissue to be used; no alterations of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue for research; and the abortion was performed in accordance with applicable State and local law.

- The principal investigator must sign a statement certifying that he or she is aware that the tissue is human fetal tissue obtained pursuant to a spontaneous or induced abortion, or pursuant to a stillbirth, that is being donated for research purposes. The principal investigator must also certify that: this information has been shared with others who have responsibilities regarding the research; and prior to eliciting informed consent from the transplantation recipient, the researcher will obtain written acknowledgement that the patient is aware of the aforementioned information. Moreover, the principal investigator will certify in writing that he or she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy that were made solely for the purposes of the research.

- Research involving the transplantation of human fetal tissue must be conducted in accord with applicable State and local law.

The institutional official must certify that the physician's statement, statement of the researcher, and the acknowledgement of the transplantation recipient will be available for audit by the Secretary, DHHS, or designee.

Confidentiality

NIH expects grantees and others involved in NIH-supported research to take appropriate actions to protect the privacy and confidentiality of individuals participating in those projects. Investigators, Data Safety Monitoring Boards, IRBs and other appropriate entities should ensure that policies and procedures are in place that protect identifying information and that they oversee compliance with those policies and procedures.

Protection of Research Subjects' Identity

Section 301(d) of the PHS Act provides that the Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research activities to protect the privacy of research subjects by withholding the names and other identifying characteristics of those subjects from individuals not engaged in the research. Authorized persons may not be compelled to disclose subjects' identities in any Federal, State, or local civil, criminal, administrative, legislative or other proceeding. An applicant may request a certificate of confidentiality to protect research subjects' identities under a specific research project. The request should be submitted to the IC GMO, and, subject to IC review and approval, a certificate may be issued pursuant to 42 CFR 2a.

TABLE II-2
SUMMARY OF ACTIONS REQUIRING NIH PRIOR APPROVAL

Activity or Expenditure Requiring NIH Prior Approval	Expanded Authorities[16] (effective 12/94)	Federal Demonstration Partnership (FDP)[17] (effective 7/00)	NIH Grants Policy Statement (NIHGPS) (effective 3/01)
Change in scope	YES	YES	YES
Preaward costs (more than 90 days prior to effective date of a new or competing continuation award)	YES	YES	YES
Preaward costs for non-competing awards	At grantee's own risk	At grantee's own risk	At grantee's own risk
Change in key personnel	YES	YES	YES
Change of grantee organization	YES	YES	YES
Change in grantee organizational status	YES	YES	YES
Addition of a foreign component under a grant to a domestic organization	YES	YES	YES
Changes to award terms and conditions or undertaking any activities disapproved or restricted as a term of award	YES	YES	YES
Carryover of unobligated balances from one budget period to the next	NO	NO	YES
Extension of final budget period of a project period	NO: one extension up to 12 months allowed with no additional funds. Must notify IC no later than 10 days prior to expiration.	NO: one extension up to 12 months allowed with no additional funds. Must notify IC no later than 10 days prior to expiration.	YES

[16] The following mechanisms are routinely included in EA/FDP: P01s, Ks, and all Rs except R43 and R41.

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Equipment purchases exceeding $25,000/unit, regardless of amount of NIH funds involved	NO, unless change in scope	NO, unless change in scope	YES
Retention of research grant funds when career (K) award made	YES	YES	YES
Alteration and renovation (A&R) (rebudgeting into A&R costs exceeding 25 percent of total approved budget for a budget period)	NO, up to (and including) $300,000 YES, if>$300,000	NO, up to (and including) $300,000 YES, if>$300,000	NO, up to (and including) $300,000 YES, if>$300,000
Transferring amounts from trainee costs	YES	YES	YES
Capital expenditures (construction, land or building acquisition)	YES	YES	YES
Need for additional NIH funding	YES	YES	YES
Closely related work	YES	YES	YES
Transfer of funds between construction and non-construction work	YES	YES	YES
Program income (use of any alternative other than that specified by NIH)	NO	NO	YES
Transferring performance of substantive programmatic work to a third party (by consortium agreement, contract, or other means)	NO, unless change in scope or the third party is a foreign organization or component	NO, unless change in scope or the third party is a foreign organization or component	YES
Incurrence of patient care costs (if not previously approved or rebudgeting additional funds into or rebudgeting funds out of this category)	NO, unless change in scope	NO, unless change in scope	YES