ATTACHMENT 4

4. PREAWARD POLICIES AND CONSIDERATIONS (PHS GPS 9505)

The preaward process begins when a PHS agency publishes a program announcement on the availability of financial assistance to carry out specified health-related activities. It continues with the preparation of the application by the entity requesting the funds, the external review of the application as applicable, and the internal PHS review. It culminates with the PHS awarding office decision on whether to award a grant.

The following sections deal with policies and procedures pertinent to the preaward phase of the grants administration process.

PROGRAM ANNOUNCEMENTS

PHS agencies are required to publish the following types of documents in either the *Federal Register* or the *NIH Guide for Grants and Contracts* for discretionary grant programs, including fellowship and training awards made directly to individuals.

- Program regulations.
- Program announcements containing the following information: Program title and Catalog of Federal Domestic Assistance (CFDA) number; program objectives, including any areas of special emphasis or interest; type of assistance--grant or cooperative agreement; description of expected PHS substantive programmatic involvement for cooperative agreements; citation of legislative authority and regulations; eligibility requirements; application deadlines and the place where applications may be submitted; consequences of late submission; requirements for review under Executive Order 12372; application format; recipient financial participation requirements; criteria for review and evaluation and program priorities for funding; the contact points for additional information; description of any program priorities for funding; and any preferences which may be given to either new or competing continuation applications.
- A statement regarding the availability of funds if not included in the program announcement.
- If other materials are available and are not included or referred to in the preceding items, a notice regarding the availability of these materials or other information the program wishes to make available to applicants.

Publication of this information enables potential applicants to determine whether to apply for funds, to understand how and by what criteria an application will be evaluated, and to know the obligations imposed on a recipient.

All PHS awarding offices are responsible for making information regarding their programs available to the interested public on request and for promoting the widespread dissemination of this information. The Grants Management Officer (GMO) is responsible for providing assistance on business management matters and grant policy issues. Project Officers are responsible for providing assistance on the programmatic aspects of the project.

ELIGIBILITY

Authorizing legislation and governing programmatic regulations specify eligibility for individual grant programs. In general, assistance is provided to nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. For-profit organizations are eligible to receive awards under all PHS financial assistance programs unless specifically excluded by legislation.

Nonprofit organizations are corporations or associations no part of whose net earnings may lawfully inure to the benefit of any private shareholder or individual. Proof of nonprofit status must be submitted by private nonprofit organizations with the application or, if previously filed with PHS, the applicant must state where and when the proof was submitted. Any of the following is acceptable evidence of nonprofit status.

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code.
- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.
- Any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

Trainees and Fellows

Trainees supported under a training grant and individuals supported under fellowships must meet the general eligibility requirements set by the particular program providing the support and any additional requirements established by the grantee institution.

To be eligible for support at the postdoctoral level (see section 7, "Trainee Costs, Stipends"), an individual must have completed all requirements for the doctoral degree before the beginning date of PHS support. Where a degree has not been formally conferred, the degree-granting institution must certify that all of the degree requirements have been met. Under training grants, the grantee must retain documentation of this certification.

Only U.S. citizens, noncitizen nationals, and those foreign nationals who possess a visa permitting permanent residence in the United States may be appointed as trainees on training grants or as individual fellows, ***(1)*** except in the case of programs specifically designed for support of foreign nationals. Individuals on temporary or student visas are not eligible to receive PHS fellowship or training grant support.

Section 504 of Public Law 90-574 allows students to be eligible to receive funds awarded for traineeships and fellowships even though they are receiving educational assistance under the Veterans Readjustment Benefits Act ("G.I. Bill").

English-Language Requirement

All applications for financial assistance and required reports submitted to awarding components of the Public Health Service must be written in the English language.

PUBLIC POLICY REQUIREMENTS

Applicants and grantees must comply with a number of public policy requirements. These policies are intended to ensure fairness, equity, and physical and other protections in activities receiving PHS financial assistance. This section lists these principal policies and cites the applicable supporting statute, regulation, or other source documents. Where requirements are applicable to subgrantees and contractors, the individual section so states.

In addition, this section explains the applicability of the particular policy to the types of programs supported by PHS. This listing is not exhaustive. Additional requirements and necessary documentation will be detailed in the application or other materials provided to applicants. Public policy provisions that are to be included in contracts under grants (or subgrants) are included in the procurement standards prescribed by 45 CFR Parts 74 and 92.

Civil Rights

Race/Ethnicity

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance, whether directly or under a subgrant or contract arrangement. The HHS regulation implementing this requirement is contained in 45 CFR Part 80. Every domestic applicant organization is required to have an Assurance of Compliance (Form HHS-690) on file with the Office for Civil Rights, Office of the Secretary, HHS, before a grant may be made to the organization. For applicant organizations that have not previously received HHS support, the proposed PHS awarding office will provide the assurance form to the applicant and will provide instructions on submitting the completed form. This requirement is also applicable to subgrantees.

Disabilities

Section 504 of the Rehabilitation Act of 1973, as amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. This requirement also applies to subgrantees and contractors under grants. The HHS regulation at 45 CFR Part 84 implements this requirement. Subpart F of that regulation applies specifically to health programs and prohibits recipients of Federal financial assistance from discriminating on the basis of handicap in the provision of benefits or services. This regulation requires an assurance by the applicant (Form HHS-690) that HHS-funded activities will be available and accessible to handicapped persons, and that there will be no discrimination in employment based on an individual's handicap. The required assurance must be on file with the Office for Civil Rights, Office of the Secretary, HHS, before a grant may be made to an organization. When such an assurance has not been filed, the PHS awarding office from which support is being sought will provide the applicant with the required form and will provide instructions as to where to send the completed form.

Age

The Age Discrimination Act of 1975 prohibits unreasonable discrimination on the basis of age in any program or activity receiving Federal financial assistance. This requirement is also applicable to subgrantees and contractors under grants. The required assurance (Form HHS-690) must be on file with the Office for Civil Rights, Office of the Secretary, HHS, before a grant may be made. The HHS regulation implementing the provisions of this Act is at 45 CFR Part 91.

Sex

All PHS grantees are encouraged to adopt practices that will eliminate sex discrimination and encourage sex fairness, including but not limited to using language that represents both genders, avoiding sex stereotyping, and representing women equitably in leadership and policymaking positions.

Title IX of the Education Amendments of 1972 (in particular, section 901 of those amendments) provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance, whether directly or under a subgrant or contract under a grant. The HHS regulation at 45 CFR Part 86 implements this requirement. The applicant (or proposed subgrantee or contractor) is required to submit an assurance (Form HHS-690) to the Office for Civil Rights, Office of the Secretary, HHS, before a grant, subgrant, or contract under a grant may be made.

Section 704 of Title VII and Section 855 of Title VIII of the PHS Act, as amended, forbids the extension of Federal support for health manpower and nurse training programs authorized under those titles to any entity that discriminates on the basis of sex in the admission of individuals to its training programs. The regulation implementing this requirement is at 45 CFR Part 83. The applicant is required to submit an assurance (Form HHS-590 or 590B) to the Office for Civil Rights, Office of the Secretary, HHS, before a grant may be made.

Alcohol and Other Drug Abuse

Section 526 of the PHS Act, as amended, provides that drug abusers who are suffering from medical conditions shall not be discriminated against in admission or treatment because of their drug abuse or drug dependence by any private or public general hospital that receives support in any form from any federally funded program. This prohibition is extended to all outpatient facilities receiving or benefiting from Federal financial assistance by 45 CFR Part 84. This prohibition also applies to subgrantees and contractors under grants.

Section 522 of the PHS Act, as amended, provides that alcohol abusers and alcoholics who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their alcohol abuse or alcoholism, by any private or public general hospital that receives support in any form from any federally funded program. This prohibition is extended to all outpatient facilities receiving or benefiting from Federal financial assistance by 45 CFR Part 84. This prohibition also applies to subgrantees and contractors under grants.

Confidentiality

Section 543 of the PHS Act, as amended, requires that records of substance abuse patients be kept confidential except under certain specified circumstances and for specified purposes. The records covered include the identity, diagnosis, prognosis, or treatment of any patient maintained in connection

with any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research that is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States. This requirement is implemented in PHS regulations at 42 CFR Part 2.

Under section 301(d) of the PHS Act, as amended, health research subjects' identities may be protected from compulsory legal process such as subpoena (with certain exceptions, such as for audit of the research project). This protection may be granted, upon application, by the PHS in the form of a certificate of confidentiality for a specific research project. The protection is issued under PHS regulations at 42 CFR Part 2a and an Interim Policy Statement issued by the Assistant Secretary for Health.

Environmental Impact

The National Environmental Policy Act of 1969 (NEPA) (Public Law 91-190) establishes national policy goals and procedures to protect and enhance the environment. This act applies to all Federal agencies and requires them to consider the probable environmental consequences of any major Federal activity, including activities of other organizations operating with the concurrence or support of a Federal agency. This includes grant-supported activities.

To administer the provisions of NEPA, PHS requires that the environmental aspects of all requests for assistance involving construction, ***(2)*** including projects involving the acquisition and/or modernization of existing buildings, and certain requests for assistance involving nonconstruction projects be reviewed and evaluated by the technical staff of the PHS reviewing office prior to approval or other action on the application. For nonconstruction project grants, PHS agency heads must determine what categories of activities or programs may have little environmental impact and should be excluded from NEPA requirements. Actions that qualify for categorical exclusions, i.e., are "screened out," will be published in the *Federal Register*.

In addition, HHS policy includes public comment and participation as a part of the environmental impact review process. Potential applicants for construction projects and nonexcluded activities under programs subject to Executive Order 12372 (see "External Review Requirements") are required to include in their notifications to the State Single Point of Contact a request for comments on the potential environmental impact of the project and to submit these comments with the completed application.

Except as provided below, all applications for construction assistance, including assistance to acquire or modernize existing buildings, shall be accompanied by the applicant's own separately bound environmental analysis to facilitate PHS review and evaluation prior to approval or other action on the application. An environmental analysis means a written review that lists the environmental effects that are expected to occur as a result of the proposed action, defines the current and future implications of these effects, and lists any proposed actions or safeguards to avoid or reduce any negative environmental effects.

For those programs or activities that have been screened out from routine NEPA processing, no environmental analysis is necessary, except in those unusual situations where a significant environmental consequence is anticipated by either the applicant or an official of the PHS awarding office. In such a case, an environmental analysis shall be provided with the application.

Flood Insurance

The Flood Disaster Protection Act of 1973 (Public Law 93-234) provides that no Federal financial assistance to acquire, modernize, or construct property may be provided in identified flood-prone communities in the United States unless the community participates in the National Flood Insurance Program and flood insurance is purchased within 1 year of such identification. The flood insurance purchase requirement is applicable to both public and private applicants for PHS support. Listings of flood-prone areas that are eligible for flood insurance are published in the *Federal Register* by the Federal Emergency Management Agency (FEMA).

Historic Properties

Under the provisions of Section 106 of the National Historic Preservation Act of 1966, the Secretary of the Interior has compiled a national register of sites and buildings of significant importance to America's history. ***(3)*** The applicant and the PHS awarding office must jointly determine whether activities using PHS financial assistance will affect a property listed in the national register. Although this requirement applies to all construction, acquisition, and modernization activities, it may also apply to other PHS grant-supported activities. This must be a preaward determination. If a designated historic property is to be affected, the applicant must obtain clearance from the appropriate State Historic Preservation Office before submitting the application.

Relocation Assistance and Real Property Acquisition

The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Public Law 91-646) requires certain assurances for those PHS financial assistance projects conducted by a State agency that involve the acquisition and/or modernization of real property or cause the displacement of persons, businesses, or farm operations. The HHS regulation implementing those provisions is at 45 CFR Part 15.

The term "State agency" means any department, agency, or instrumentality of a State. For the purposes of 45 CFR Part 15, this includes the State itself, a political subdivision of a State, State or local institutions of higher education or hospitals, and any department, agency, or instrumentality of two or more States. This term also includes a private entity when such an entity receives PHS funds to act as an agent or contractor of a State agency in the discharge of the State agency's responsibilities. Indian tribes and tribal organizations are also subject to these requirements.

The applicant must ensure that fair and reasonable relocation payments and advisory services will be provided to displaced persons and that safe, decent, and sanitary replacement dwellings will be available to such persons within a reasonable period of time prior to displacement. The State agency must be guided by the real property acquisition policies of the Act, and the property owners must be paid or reimbursed for necessary expenses as specified by the Act. These assurances must be contained in or accompany all applications that are subject to this policy.

Additional details regarding this requirement are contained in 45 CFR Part 15.

Elimination of Architectural Barriers to the Handicapped in Construction Supported by Grant Funds

All grants for construction of new facilities ***(4)*** must include provisions for making the facilities accessible to and usable by the physically handicapped. Where assistance is provided for alteration or renovation (including modernization and expansion) of existing facilities, the altered facility (or part of

the facility) must include such provisions to the maximum extent feasible. Minimum standards for facilities used by the handicapped are contained in "Specifications for Making Buildings and Facilities Accessible to and Usable by the Physically Handicapped" (American National Standards Institute, Inc. A.117.1, 1961; reaffirmed 1971) **(5)**. These minimum standards must be included in the specifications for any PHS-funded new construction unless the grantee proposes to substitute standards that meet or exceed these standards.

These standards must also be included to the maximum extent feasible in the specifications of any PHS-funded renovation. Applicants for such assistance must ensure that the facility will comply with these standard specifications (see discussion of 45 CFR Part 84 in "Civil Rights, Disabilities"). The applicant will be responsible for conducting inspections to ensure compliance with these specifications by any contractor performing construction services under the grant.

The only exception to this requirement is in those programs where the governing legislation may proscribe the inclusion of special provisions for the handicapped.

Human Subjects

Section 474(a) of the PHS Act, implemented by 45 CFR Part 46, requires basic protection for human subjects involved in PHS grant-supported research activities. A human subject is defined in the regulation as "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information." The regulation extends to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The regulation also specifies additional protections for certain classes of human research involving fetuses, pregnant women, human *in vitro* fertilization, and prisoners. However, the regulation exempts certain categories of research involving human subjects which normally involve little or no risk. The exemptions are listed in 45 CFR Part 46.101(b).

Research is defined in 45 CFR Part 46 as "systematic investigation designed to develop or contribute to generalizable knowledge." Activities meeting this definition constitute research for purposes of applying the regulation even if they are supported by a grant which might have as its overall purpose an activity that is not primarily research. For example, some demonstration, training, and service programs may include research activities.

Research activities may involve interaction with the individual or intervention or may entail only the obtaining of identifiable private information. "Interaction" includes both physical procedures by which data are gathered or generated and manipulations of the subject or the subject's environment that are performed for research purposes. "Private information" is covered by the regulations when the information is individually identifiable and the information is either about the individual's behavior in a context in which there is reasonable expectation that no observation or recording is taking place or is information provided for specific purposes with the reasonable expectation that it will not be made public (e.g., a medical record).

Research covered by 45 CFR Part 46 will not be funded unless it has been reviewed and approved by an institutional review board (IRB). In order to approve research covered by the regulation, the IRB shall determine that all of the following requirements are satisfied.

- Risks to subjects are minimized by --

  - Using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk.

  - Whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to subjects are reasonable in relation to expected benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

- Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

- Informed consent is sought from each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by the regulation.

- Informed consent is appropriately documented in accordance with and to the extent required by the regulation.

- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- Where appropriate, provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

- Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged, appropriate additional safeguards are included in the study to protect the rights and welfare of these subjects.

The institution which receives or is accountable for a PHS grant has primary responsibility for safeguarding the rights and welfare of individual human subjects involved in research activities supported by the grant. In regard to project grant awards, institutions applying for PHS awards for nonexempt human subject research are required to provide written Assurances of Compliance with 45 CFR Part 46 and to file with the application a certification (Form HHS 596) that the proposed research activity has been reviewed and approved by an IRB in compliance with 45 CFR Part 46.

Certain types of applications for project grant awards, such as institutional type grants, research training grants, or projects that require completion of prior scientific studies, are submitted with the knowledge that human subjects may be involved within the period of funding, but definite plans are not set forth in the application. Before human subjects may be involved in nonexempt research activities supported by these awards, the research activity must be reviewed and approved by an IRB and a certification (Form HHS 596) submitted to PHS. With regard to block grant awards, no human subjects may be involved in nonexempt research activities supported by block grants unless the research activity has been reviewed and approved by an IRB established in compliance with 45 CFR Part 46. No individual may receive PHS grant funds for nonexempt human subjects research unless the individual is affiliated with or sponsored by an institution that assumes responsibility for the research under a written Assurance of Compliance or the individual makes other arrangements with PHS.

Before award, PHS staff (or other application reviewers) are responsible for determining independently whether human subjects are involved, whether the research is exempt, and whether protections for the subjects are adequate. The Office for Protection From Research Risks, National Institutes of Health,

Bethesda, MD 20892, is responsible for the implementation of, and compliance with, 45 CFR Part 46 for HHS. Information concerning the preparation and negotiation of assurances as well as copies of the regulation may be obtained from that office.

Sterilization

HHS and PHS have established certain limitations on the performance of nonemergency sterilizations by PHS grant-supported programs or projects that are otherwise authorized to perform such sterilizations. PHS has issued regulations that establish safeguards to ensure that such sterilizations are performed on the basis of informed consent and that the solicitation of consent is not based on the withholding of benefits. These regulations, published at 42 CFR Part 50, Subpart B, apply to the performance of nonemergency sterilizations on persons legally capable of consenting to the sterilization.

Federal financial participation is not available for any sterilization procedure performed on an individual who is under the age of 21, legally incapable of consenting to the sterilization, declared mentally incompetent, or institutionalized. The requirements in this section also apply to subgrantees and contractors under grants.

Abortions and Related Medical Services

Federal financial participation is generally not available for the performance of an abortion in a grant-supported health services project. This limitation also applies to subgrantees and contractors under grants. For further information on this subject, consult the regulation at 42 CFR Part 50, Subpart C.

Recombinant DNA and Institutional Biosafety Committees

Each institution where research involving recombinant DNA technology is being or will be conducted must establish a standing Biosafety Committee. Requirements for the composition of such a committee are given in Section IV of *Guidelines for Research Involving Recombinant DNA Molecules* (49 FR 46266 or latest revision), ***(6)*** which also discusses the roles and responsibilities of principal investigators and grantee institutions. A roster of the members of the Institutional Biosafety Committee must be submitted to the Office of Recombinant DNA Activities (see address below). At a minimum, this should include the names, addresses, occupations, and qualifications of the chairpersons and members of the committee.

The committee is required to review each proposed nonexempt project for recombinant DNA experiments and certify that it has found the procedures, project, personnel, and facilities adequate and in compliance with NIH Guidelines. *Guidelines for Research Involving Recombinant DNA Molecules* should be consulted for complete requirements for the conduct of projects involving recombinant DNA technology. This requirement is also applicable to subgrantees and contractors under grants.

Animal Welfare

The *PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions* requires that applicant organizations establish and maintain appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by PHS. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal

care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the *Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, MD 20892, 301-496-7005*.

The policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes." An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with OPRR. As part of this assurance, which commits the applicant organization to comply with the PHS policy, the applicant organization must appoint an institutional animal care and use committee (IACUC), which is required to review and approve those sections of applications for PHS support that involve vertebrate animals.

As an agent of the institution with respect to PHS-supported activities, the IACUC shall --

- Review at least once every 6 months the institution's program for humane care and use of animals using the *Guide* as a basis for evaluation.
- Inspect at least once every 6 months all of the institution's animal facilities (including satellite facilities) using the *Guide* as a basis for evaluation.
- Prepare reports of the IACUC evaluations conducted as required by the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (hereinafter referred to as "the Policy") and submit the reports to the Institutional Official. The reports shall be updated at least once every 6 months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OPRR upon request. The reports must contain a description of the nature and extent of the institution's adherence to the *Guide* and the Policy and must identify specifically any departures from the provisions of the *Guide* and the Policy, stating the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with the Policy and in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) or another accrediting body recognized by PHS, the report should identify those facilities as such.
- Review concerns involving the care and use of animals at the institution.
- Make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.
- Review and approve, require modifications in (to secure approval), or withhold approval of those components of PHS-supported activities related to the care and use of animals as specified in the Policy.
- Review and approve, require modifications in (to secure approval), or withhold approval of

proposed significant changes regarding the use of animals in ongoing activities.

- Be authorized to suspend an activity involving animals in accordance with the specifications set forth in the Policy.

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by PHS to the IACUC for further review in the case of apparent or potential violations of PHS policy. Copies of the approved Animal Welfare Assurance are available to every researcher at the applicant organization.

No award to an individual will be made unless that individual is affiliated with an organization that accepts responsibility for compliance with PHS policy and has filed the necessary assurance with OPRR.

Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

Reporting Requirements

At least once every 12 months, the IACUC, through the Institutional Officer, shall report in writing to OPRR --

- Any change in the institution's program or facilities that would place the institution in a different category than that specified in its assurance.
- Any change in the description of the institution's program for animal care and use.
- Any changes in the IACUC membership.
- The dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Institutional Official.

At least every 12 months, the IACUC, at an institution which has no changes to report, shall submit a letter, through the Institutional Official, to OPRR stating that there are no changes and informing OPRR of the dates of the required IACUC evaluations and submissions to the Institutional Official.

The IACUC, through the Institutional Official, shall promptly provide OPRR with a full explanation of the circumstances and actions taken with respect to.

- Any serious or continuing noncompliance with the Policy.
- Any serious deviation from the provisions of the *Guide.*
- Any suspension of an activity by the IACUC.

Reports filed as required by the Policy shall include any minority views filed by members of the IACUC.

Investigator's Responsibility

Research investigators are entrusted with an essential role in assuring the humane care and use of animals. In activities they conduct or which are conducted under their direction, they have a direct and continuing responsibility to see that animals are adequately cared for and used. Investigators must comply with the PHS Policy, with the applicant organization's Animal Welfare Assurance, and with the requirements and determinations of the IACUC concerning the conduct of the research. Investigators must ensure that discomfort, distress, pain, and injury to the animals are avoided or minimized, consistent with a sound research design; that no more animals are used than are necessary to reach sound scientific conclusions; and that, when appropriate, animals are painlessly sacrificed in accordance with methods of euthanasia approved by the Panel on Euthanasia of the American Veterinary Medical Association.

Student Unrest Provisions

No funds appropriated under the HHS Appropriations Act shall be used to provide a loan, loan guarantee, grant, salary, or any remuneration whatever to any individual applying for admission, attending, employed by, teaching at, or doing research at an institution of higher education who has engaged in conduct on or after August 1, 1969, that involves the use of (or the assistance to others in the use of) force, the threat of force, or the seizure of property under the control of an institution of higher education to require or prevent the availability of a certain curriculum or to prevent the faculty, administrative officials, or students in such institution from engaging in their duties or pursuing their studies at such institution. This prohibition stems from language in HHS's annual appropriations act.

The primary responsibility for observing and complying with the terms of this provision rests with the institutions of higher education receiving PHS awards or, where payments are made directly, with the individuals receiving such payments. Fair notice shall be given to an affected individual of any proposed cessation of payment, and an opportunity for a hearing shall be provided.

Misconduct in Science

It is the policy of PHS to require high ethical standards in all grant-supported projects and to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent misconduct in science. Recipient institutions shall report promptly to the head of the appropriate PHS awarding component incidents of alleged or apparent misconduct in science that are judged to warrant investigation by a recipient institution. Issues involving potential criminal violations, such as misappropriation of Federal funds, must be promptly reported to the HHS Office of the Inspector General. (See regulations contained in 42 CFR Part 50, Subpart A.)

Requirements for Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) requires that, effective March 18, 1989, all grantees of any Federal agency certify to that agency that they will maintain a drug-free workplace or, in the case of grantees who are individuals, certify to the agency that their conduct of grant activity will be drug free. HHS regulations implementing this Act, set forth in 45 CFR Part 76 entitled *Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)*, were published in the *Federal Register* on January 13, 1989. These regulations require that grantees take steps to provide a drug-free workplace in accordance with the Act.

Grant application forms have been revised to include a specific assurance from applicants that a drug-free workplace will be provided. The main points of the certification require the applicant organization to --

- Publish a statement notifying employees that the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance is prohibited in the workplace and specifying the actions that will be taken against employees for violation of such prohibition.
- Establish a drug-free awareness program.
- Require that each employee engaged in the performance of a grant or contract be provided a copy of the published statement.
- Notify employees that as a condition of employment, they will abide by the terms of the statement.
- Notify the PHS awarding office of any employee convicted of a drug violation occurring in the workplace.
- Require any employee who is convicted of a drug offense occurring in the workplace to participate in a rehabilitation program.

Debarment and Suspension

Executive Order 12549, Debarment and Suspension, of February 18, 1986, called for development of a governmentwide debarment and suspension system for nonprocurement transactions with Federal agencies. "Nonprocurement transactions" include, for example, grants, cooperative agreements, scholarships, fellowships, and loans. Accordingly, applicants (defined as primary participants) submitting applications for financial assistance from PHS are required to certify that, to the best of their knowledge and belief, neither they, their principals, nor their research personnel.

- Are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency.
- Have, within a 3-year period preceding this 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; violation of Federal or State antitrust statute; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property.
- Are 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.
- Have, within a 3-year period preceding this application, had one or more public transactions (Federal, State, or local) terminated for cause or default.

Subawardees, that is, other corporations, partnerships, or other legal entities (defined as lower tier participants), are required to make the same certifications to the applicant organization concerning their covered transactions.

Application forms have been revised to include a specific item concerning this assurance.

Debt Collection

The Federal Claims Collection Standards (4 CFR Parts 101-105) require that, except where prohibited by law, PHS charge interest on all delinquent debts owed to PHS by grantees. Unless otherwise specified in law, regulation, or award instrument, debts are considered delinquent 30 days after notification to the grantee of the indebtedness. The interest on debts that become delinquent will be computed from the date of the original notification to the grantee of the indebtedness. The rate will be at the higher of the Current Value of Funds Rate or the private consumer rate of interest fixed by the Department of the Treasury. Penalties and administrative costs of collection shall also be charged to grantees other than State and local governments in accordance with the Debt Collection Act of 1982. The Act has been implemented through the HHS Claims Collection Regulations (45 CFR Part 30, Subpart B) as follows:

- A penalty charge of 6 percent a year will be assessed on debts that are more than 90 days overdue. Penalty charges will accrue from the date the debt became overdue until the overdue amount is paid.

- Delinquent debtors will be assessed charges to cover the Government's administrative costs of collecting overdue debts. From time to time, PHS will publish a notice in the *Federal Register* setting forth the amounts to be assessed for administrative collection costs.

Should a grantee appeal a monetary adverse determination under 42 CFR Part 50, Subpart D, and/or 45 CFR Part 16, collection will be suspended pending a final decision on the appeal. If the determination is sustained (either fully or partially), interest will be charged beginning with the date of the original notification to the grantee of the indebtedness.

Certification of Nondelinquency on Federal Debt

Office of Management and Budget (OMB) Memorandum M-87-32, Certification of Nondelinquency by Applicants for Federal Assistance, requires that before a grant can be awarded, the applicant organization must certify that it is not delinquent on the repayment of any Federal debt. The certification applies to the applicant organization, not to the person signing the application as the authorized representative nor to the principal investigator/program director.

Where the applicant discloses delinquency on debt to the Federal Government, the PHS shall (a) take such information into account when determining whether the prospective grantee organization is responsible with respect to that grant and (b) consider not making the grant until payment is made or satisfactory arrangements are made with the agency to which the debt is owed. Therefore, it may be necessary for PHS to contact the applicant before a grant can be made to confirm the status of the debt and ascertain the payment arrangements for its liquidation. Applicants who fail to liquidate indebtedness to the Federal Government in a businesslike manner place themselves at risk of not receiving financial assistance from PHS.

Lobbying

Section 319 of Public Law 101-121 amends Title 31, United States Code, by adding a new Section 1352, entitled "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions."

Section 1352 generally prohibits recipients of Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a *specific* grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (nonappropriated) funds. These requirements apply to grants and cooperative agreements *exceeding* $100,000. (See interim final rule contained in 45 CFR Part 93.)

Program Fraud Civil Remedies Act

The Program Fraud Civil Remedies Act of 1986, Public Law 99-509, provides for the imposition of civil penalties against persons who make false, fictitious, or fraudulent claims to the Federal Government for money (including money representing grants, loans, or other benefits). A civil penalty of not more than $5,000 may be assessed for each such claim. Also, if the Government has made any payment on such false or fraudulent claim, an assessment of not more than twice the amount of such claim may be made in lieu of damages. Regulations contained in 45 CFR Part 79 specify the administrative procedures for imposing civil penalties and assessments and the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

False Claims Act

The False Claims Act, as amended, 18 U.S.C. 287 and 100l, provides that whoever makes or presents any false, fictitious, or fraudulent statements or representations or claims against the United States shall be subject to imprisonment of not more than 5 years and shall be subject to a fine in the amount provided by 18 U.S.C. 287.

PHS Metric Program

Public Law 94-168, Metric Conversion Act of 1975 (Title 15, U.S.C., Sections 205a through 205k), states that the policy of the United States shall be to coordinate and plan the increasing use of the metric system in the United States.

Public Law 100-418, Omnibus Trade and Competitiveness Act of 1988, Section 5164 (Title 15, U.S.C., Sections 205a through 205k) amended the Metric Conversion Act of 1975 to provide that.

- The metric system of measurement is the preferred system of weights and measures for U.S. trade and commerce.
- Each Federal agency shall, by a date certain and to the extent economically feasible by the end of FY 1992, use the metric system of measurement in its procurements, grants, and other business-related activities (unless metric usage is impractical or would have an adverse impact on the market share of U.S. firms).
- Agencies shall seek ways to increase understanding of the metric system of measurement through educational information and guidance and in Government publications.

Consistent with governmentwide implementing regulations issued at 15 CFR Part 19, Subpart B, and/or any other governmentwide requirements, it is PHS policy to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and other financial assistance awards.

Effective October 1, 1991, applications for grants, cooperative agreements, and other financial assistance submitted to PHS awarding offices are required to use metric units. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric units.

Pro-Children Act of 1994

Public Law 103 227, Part C - Environmental Tobacco Smoke, also known as the Pro Children Act of 1994, imposes restrictions on smoking where Federally funded children's services are provided. With respect to PHS funded activities, it specifically requires that, for all awards made on or after December 26, 1994, smoking should be prohibited in any indoor facility owned, leased, or contracted for and used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking should be prohibited in any indoor facility or portion of a facility owned, leased, or contracted for and used for the routine or regular provision of health care, day care, or early childhood development (Head Start) services to children under the age of 18. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such Federal funds. These requirements are applicable if the services are funded by PHS either directly or through State or local government, by grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment and facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Applicants covered by the provisions of this Act are required to certify in the application that they will comply with the requirements of the Act. Grantees must obtain the same certification from subrecipients.

PHS Policy on Smoke-Free Workplace

PHS strongly encourages all recipients of its grants to provide smoke-free workplaces and promote the nonuse of tobacco products. Doing so is consistent with both the mission of PHS and that of its partners, the PHS grantees, to protect and advance the physical and mental health of the American people. PHS 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 space.

Veterans Health Care Act of 1992

Section 602 of the Veterans Health Care Act of 1992 (Public Law 102-585) established section 340B of the Public Health Service Act, Limitation on Prices of Drugs Purchased by Covered Entities. Section 340B provides that, effective December 1, 1992, certain health services delivery grantees of PHS, as specified therein (referred to as covered entities), shall receive drug discounts from drug manufacturers for outpatient drugs (as defined in section 1927(k) of the Social Security Act). Information on the drug discount program (e.g., covered entities, covered drugs, and discount amount) may be obtained from the Office of Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, 10th floor, Bethesda, MD 20814 or the awarding office funding the program.

Certain covered entities must be certified by the Secretary of HHS before they become eligible for the drug discount prices. The entities requiring certification are those that (a) receive grant funds related to

the treatment of sexually transmitted diseases, (b) receive grant funds for the treatment of tuberculosis, or (c) receive certain assistance under Title XXVI of the PHS Act. Additional information about this certification may be obtained from the applicable PHS program directors.

Section 340B contains prohibitions relating to drug diversion which might require covered entities to develop alternative drug management systems. HHS has identified three potential problem areas concerning drug diversion: (a) nonpatients of the covered entity (e.g., individuals, other than patients of the entity, who obtain covered outpatient drugs from the pharmaceutical dispensing facility), (b) ineligible entities within the same facility (e.g., a large hospital or health department containing many clinics only several of which are covered entities), and (c) excluded services of the covered entity (e.g., inpatient services).

Covered entities that wish to participate in the drug pricing program are required to utilize separate drug purchasing and dispensing systems for covered services or alternative tracking systems that have been approved by HHS. These systems will be necessary to avoid potential drug diversion problems and provide adequate documentation for audit purposes.

An additional aspect of this legislation that affects grantees is the Omnibus Budget Reconciliation Act of 1990. This Act requires drug manufacturers to provide rebates to State Medicaid agencies for outpatient drugs dispensed under the Medicaid program. The Veterans Health Care Act also requires drug manufacturers to provide discounts to the covered entities. This results in the potential for double price reductions.

PHS, in cooperation with the Health Care Financing Administration, HHS, has developed a mechanism to prevent double price reductions. To the extent that covered entities do not bill Medicaid or utilize all-inclusive rates (per encounter or visit), duplicate discounts and rebates will not occur. For other entities billing on a cost basis for drug purchases, PHS gives a list of their Medicaid provider numbers to State Medicaid agencies. Therefore, those entities utilizing cost-based billing systems who wish to participate in the program must provide their Medicaid provider numbers to the Office of Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, for forwarding to the State Medicaid agencies.

Subject to the procedures established by PHS, a drug manufacturer will be permitted to audit the records of covered entities regarding possible duplicate discounts and the resale of drugs to persons who are not patients of the entity. If the covered entity is found in violation (after notice and hearing) of either the resale or transfer of drugs or the duplicate discount/rebate, it may result in sanctions such as being eliminated from participation in the drug discount program.

USES OF APPLICANT INFORMATION

Following are policies that organizations should be aware of when they apply for Federal financial assistance. These policies are of a general nature, and their applicability extends beyond the preaward stage. Applicability is specified in each section, as necessary, to distinguish between types of awards and types of grants.

Release of Information

The Freedom of Information Act

The Freedom of Information Act (FOIA) (Public Law 90-23) as amended and associated public

information regulations of HHS (45 CFR Part 5) require the release by PHS of certain grant documents and records requested by members of the public. These policies and regulations apply to information in the possession of PHS and do not require recipients or contractors under grants to permit public access to their records.

The following types of material will generally be released:

- Funded applications
- Approved and disapproved noncompeting continuation applications
- Notices of Grant Award
- Financial Status Reports
- Final reports of any audit, survey, review, or evaluation of grantee performance that have been transmitted to the grantee organization

The organization that submitted the application will be notified of a Freedom of Information request through the project director or principal investigator by the appropriate PHS FOIA office and will be given an opportunity to identify potentially patentable or commercially valuable information that should not be disclosed if PHS has substantial reason to believe that information in the records could reasonably be considered exempt under Exemption 4. After PHS consideration of the grantee's submission, the grantee will be informed of the agency's decision as to what documents and to whom the documents will be released.

The following types of records or information will generally be withheld in response to an FOIA request.

- Pending grant applications
- Unfunded new and competing continuations and competing supplemental applications
- Financial information regarding a person, such as salary information pertaining to project personnel
- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- Opinions in interagency or intraagency memoranda or letters expressed by Government officers, employees, or consultants
- Trade secrets and commercial, financial, and otherwise intrinsically valuable information that are obtained from a person or organization and are privileged or confidential; information, the release of which would adversely affect the competitive position of the person or organization, and patent or other valuable commercial rights of the person or organization

If a document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted by a designated PHS or HHS FOIA Officer, and the balance of the record will be disclosed.

The Privacy Act

The Privacy Act of 1974 (Public Law 93-579) provides certain safeguards for individuals against invasions of personal privacy. These safeguards include the right of individuals to determine what information about them is maintained in Federal agencies' files and how that information is used and the right of individuals to have access to such records and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated.

The Act also imposes requirements on Federal agencies with respect to the manner in which they collect, use, disseminate, and maintain records containing information pertaining to specific individuals. For example, information obtained for one purpose cannot be used for other purposes without the concerned individual's consent.

Records maintained by PHS with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act and the implementing regulation issued by HHS (45 CFR Part 5b) if they constitute a "system of records" as defined in that regulation. Records maintained by grantees are not subject to the requirements of 45 CFR Part 5b.

The consideration of a request for information concerning an individual, made by a party other than the subject individual, will take into account both the right to know of the requester (under the Freedom of Information Act) and the right to privacy of the individual to whom the record pertains (under the Privacy Act).

Salary Information in Application

Applicant organizations shall have the option of omitting specific salary rates or salary amounts for individuals from copies of grant applications that are made available to outside reviewers. For this purpose, the term "outside reviewers" refers to persons who are not regular employees of PHS. This option would apply to types of applications subject to objective review requirements, e.g., new applications and competing continuation applications, under programs where personnel costs are required to be shown by position. When an applicant exercises this option, the following conditions shall apply:

- Specific salary rates must be included in or attached to one copy of the application which will be restricted to use by PHS employees.
- All other copies, which will be made available to outside reviewers, should show undetailed salary summary totals but must include at least the following information for each individual who is identified in the application as working or expected to work on the grant-supported activity:
    - The name of the individual if known and the position or job title.
    - Percentage of time or effort or hours per week expected to be devoted to work on the project.
    - Whether or not salary support is requested from the grant.

Under some programs, applicants (primarily nongovernmental applicants) are also required to submit other types of confidential information to PHS in their applications, such as information about the applicant organization's financial status or structure.

Any confidential information, including salary information, need not be included with applications submitted to State Single Points of Contact under Executive Order 12372 for review, but an identification of any items withheld should be attached to those copies.

Information Collection Under Grants

The use of grant funds for the collection of information is governed by the following criteria:

- No grant shall be awarded with a primary objective of collecting information intended primarily for use by the Government or third parties specifically designated by the Government. Contracts shall be used for this purpose unless a grant is specifically required by legislation.
- Recipients may use PHS grant funds to collect information under the following conditions:
    - When the collection of information is not a primary objective of the grant but is incidental to, or is an integral part of, a grant-supported activity.
    - When the collection of information is a primary objective of the grant, but such information is not intended primarily for the use of the Government or a party designated by the Government.

When information is collected according to either of the two conditions above, recipients are prohibited from representing to their respondents that the information is being collected for, or in association with, the Federal Government unless PHS awarding office approval has been obtained and OMB report clearance procedures as contained in OMB regulations at 5 CFR Part 1320, Controlling Paperwork Burdens on the Public, have been followed where required. (When OMB approval is required, the PHS awarding office is responsible for obtaining the necessary prior clearance.)

OMB clearance is required whenever PHS sponsors the use of a reporting form or plan to collect identical kinds of information or data from 10 or more persons. A reporting form or plan used by a grantee is considered to be sponsored by PHS when one or more of the following circumstances exist:

- The PHS awarding office authorizes the recipient to represent to respondents that the information is being collected for, or in association with, PHS.
- The recipient uses the report form or plan to collect information that PHS has requested for the planning, operation, or evaluation of its program.
- The terms of the award provide for PHS awarding office approval of the study design, questionnaire content, or data collection procedure.
- The terms of the award provide for either submission of the data for individual respondents or the preparation and submission of special requested tabulations to the PHS awarding office.

PHS and OMB approval may also be required if the use of a report form or plan presents a relatively high risk of unwarranted invasion of privacy.

Collection of the following types of information is not subject to the clearance requirements under OMB regulations at 5 CFR Part 1320:

- Health professions data as described in Section 708 of the PHS Act, as amended.
- Tests or examinations given individuals for determining knowledge, abilities, or aptitudes of the person tested and the collection of information for identification or classification in connection with such tests.
- Information from patients that is to be used exclusively for the purpose of research on or direct treatment of a clinical disorder or for the interpretation of biological analyses of body fluids, tissues, or other specimens, or for identification or classification of such specimens. (See 5 CFR Part 1320 for additional exemptions from clearance requirements.)

EXTERNAL REVIEW REQUIREMENTS

The following sections deal with required reviews by organizations outside PHS of certain types of applications and requests for support. Where required under discretionary grant programs, these reviews must be completed prior to the PHS review of an application. The reviews discussed below are in addition to reviews that may be legislatively mandated for certain programs.

Executive Order 12372

Executive Order 12372 (Intergovernmental Review of Federal Programs) established a process for consulting with State and local officials on proposed Federal assistance. HHS has implemented the Executive Order through regulations at 45 CFR Part 100 (Intergovernmental Review of Department of Health and Human Services Programs and Activities). The objectives of the process are to increase State flexibility to design a consultation process and select the programs it wishes to review, increase the ability of State and local elected officials to influence Federal decisions, and compel Federal officials to be more responsive to State concerns or explain the reasons. State and local officials are given 60 days to review and comment upon new and competing continuation applications and 30 days to review and comment upon noncompeting continuation applications.

Applicants should contact the Governor's office for information regarding the particular consultation (review) process designed by their State. For the latest list of programs covered by the Executive Order, contact the awarding office GMO.

Public Health System Reporting Requirements

Community-based, nongovernmental organizations applying for health services grants will be notified in the application materials if the program is subject to the Public Health System Reporting Requirements. Such applicants shall submit a copy of the application face page (SF-424) and a one-page summary of the project, called the Public Health System Impact Statement (PHSIS), to the heads of the appropriate State and local health agencies (health department, department of mental health, department of hygiene, etc.), as determined by the applicant, no later than the Federal application receipt deadline date.

The PHSIS and SF-424 application face page must be submitted in conjunction with all new and competing continuation applications and the first noncompeting continuation application in the initial project period or any extension thereof.

The PHSIS must be no more than one page in length and shall address the extent to which a proposed project affects, and is related to, existing community services. The PHSIS shall include the following information, which may be taken from the application's Program Narrative:

- A description of the population to be served whose needs would be met under the proposal
- A summary of the services to be provided
- A description of any coordination planned with the appropriate State or local health agency(ies)

INTERNAL REVIEW PROCESS

Application Receipt

Except for applications processed through the NIH Division of Research Grants, the GMO is the central point for receipt and initial processing of all grant applications and related documents for all programs serviced by that GMO.

Competing applications, i.e., those subject to independent objective review requirements (see below) will be considered "on time" if they are received on or before the established deadline date or sent on or before the deadline date given in the program announcement or in the application kit materials, unless they arrive too late for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing. Late competing applications not accepted for processing may either be returned to the applicant or held for the next regularly scheduled review cycle.

Applications for noncompeting continuation awards will be considered on time if they are sent by the established deadline date unless received too late for orderly processing. The late submission or receipt of a noncompeting continuation application will result in a delay in the issuance of the continuation award during which time no additional Federal funds will be awarded.

Grant applications processed through NIH's Division of Research Grants (DRG) must be received by the published application receipt dates. However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than 1 week prior to the deadline date. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day. The receipt date will be waived only in extenuating circumstances. To request such a waiver, an explanatory letter must be included with the signed completed application. No waiver will be granted prior to the receipt of the application.

A designated PHS official may determine that a competing or noncompeting application is nonconforming if it cannot be properly evaluated or its deficiencies cannot be remedied before award, thereby ending the review process for that application. For this purpose, a "nonconforming application" is one that does not meet the requirements of the program announcement to which it is responding because it omits required material or contains material not permitted under the announcement, is submitted by an ineligible applicant, or omits any assurance or other document required to be submitted with the application. PHS will return nonconforming applications to the applicant. Correction of the deficiencies in noncompeting applications should be made as soon as possible, and the application should be returned to the PHS awarding office in order to expedite the processing of the application.

An applicant may withdraw an application from consideration at any time. A competing application that is withdrawn by the applicant before it enters the formal review process will be returned to the applicant. Other applications may be returned to the applicant at the discretion of the PHS awarding office.

Objective Review of Grant Applications

All PHS discretionary grant programs, including construction programs when awards are made on the basis of competitive review and fellowships and other training programs when awards are made to individuals, have established systems of objective review. Within each of these programs, all new, competing continuations, and competing supplemental applications must compete for funding and receive an independent objective review.

The review includes a thorough and consistent examination of each application by persons knowledgeable in the field for which support is requested, who have no direct relationship with the organization or individual submitting the application, and who do not have any personal or vested interest in the award of a grant to that organization or individual. Peer review, a system using reviewers who are the professional equals of the principal investigator or program director who is to be responsible for directing or conducting the proposed project, is a form of objective review. Peer review is legislatively mandated in some programs and in other programs is administratively required.

The objective review is generally conducted by a committee or groups of field readers or by a combination of those methods. Reviewers may be Federal or non-Federal. Peer review committee membership is usually entirely non-Federal. The use of non-Federal reviewers is governed by the requirements of the Federal Advisory Committee Act and its implementing HHS regulations, 45 CFR Part 11.

Objective review of grant applications is intended to be advisory and not to replace the authority of the PHS awarding official to decide whether a grant shall be awarded. A review committee makes a recommendation for approval or disapproval, but the decisionmaking official has the sole authority to fund an application. Such decisions are based not only on the recommendations resulting from the objective review process but also on stated programmatic priorities, the availability of funds, Executive Order 12372 decisions and recommendations, where applicable (see "External Review Requirements"), and other information available to the awarding official.

Cost Analysis

A cost analysis is normally performed for every grant application approved for funding by PHS except for awards such as fellowships, which do not require detailed budgets. A cost analysis involves obtaining cost breakdowns, verifying cost data, evaluating specific elements of cost, and examining data to determine necessity, reasonableness, and allowability of the cost reflected in the grant budget. The GMO of the PHS awarding office responsible for reviewing the application will determine the form and extent of the cost analysis based on information obtained from the review process, the amount and type of costs being requested, the nature of the project, and past experience with the applicant institution.

Reviews of Financial Systems and Management Capability

In cases where a prospective grantee has had no prior Federal grants or cost-type contracts, the applicant's financial management system and management capability must be reviewed before award or within a reasonable time thereafter to ensure its adequacy and acceptability and to aid the PHS awarding office in determining the organization's capability for financial stewardship of Federal funds.

In order to assess the applicant/grantee's management capability and to assist in monitoring the project, the GMO may require the submission of the following types of information:

- Grantee administrative directives, organization charts, manuals, etc.
- Corporate charter and bylaws, financial statements, IRS Tax Exemption Certification, etc.
- Grantee accounting manuals, charts of accounts, procedures, etc.
- Grantee personnel policies and directives
- Grantee travel policies
- Grantee procurement procedures and property management instructions
- Overall institutional audit reports affecting an individual grant or a number of grants
- Information on indirect cost rates, items included in indirect cost pools, etc.
- Copies of, or references to, awards with special conditions (including awards from other agencies), terminations, and any other useful background information

A review of an applicant's or grantee's financial management systems may also be undertaken if any of the following conditions exist:

- The organization may have had prior Federal grants or cost-type contracts but will be receiving PHS support for the first time.
- The organization is known to have operational and/or financial problems in its dealings with commercial or governmental entities.
- The PHS award will result in a major change in the organization's overall operation.
- The PHS awarding office is aware of information which raises doubts about the adequacy of the organization's financial and business management capabilities.

The decision whether to have a review and, if so, how comprehensive it should be is made by the responsible GMO. That official may conduct the review or have others conduct it. The review is made against the standards for recipient financial systems in 45 CFR Part 74, Subpart H.

PHS policy is to make awards to organizations which are competently managed, are responsible, and are committed to achieving the objectives of the grants they receive. However, experience has shown that a few organizations either have performed inadequately with respect to the management and use of PHS grant funds or have serious potential deficiencies in business management systems. If an award is proposed to such an organization, in order to ensure proper stewardship of Federal funds and to assist the recipient in taking corrective action as quickly as possible, the organization should be designated as an "Exceptional Organization".

An exceptional organization is defined as one that shows evidence of poor business management practices. Once an organization has been identified as exceptional, either during the review of an application or any time during the life of the project, the PHS awarding office shall provide close monitoring and assistance as deemed appropriate by the GMO. In some cases, the GMO may impose special grant conditions on the Notice of Grant Award as provided by 45 CFR Part 74.7, 45 CFR Part 74.72(e), and 45 CFR Part 92.12.

Notification to Unsuccessful Applicants

Within 30 days after the decision not to fund an application, a written notice must be sent to each applicant whose application has been disapproved or has been recommended for approval but is not expected to be funded during the current funding cycle. The notice must provide the reasons the application will not be funded or the name of an official to contact for more information. Notices shall also be sent to applicants whose applications have been deferred, i.e., where a final recommendation has not been made in order to obtain additional information or otherwise augment the review of an application.

An application that has been recommended for approval but is not funded in a particular review cycle may be considered for funding in subsequent review cycles. Such applications must then compete for funding with comparable applications recommended for funding in that review cycle. An applicant whose application is recommended for approval but is not funded will be advised whether and for what period of time the application will be held for reconsideration and possible funding. In no case may such an application be held for reconsideration for more than 12 months in an approved but unfunded status following the date of the funding decision. This policy is applicable to all PHS discretionary grant programs, both construction and non-construction.

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(1) Individual fellows must have been lawfully admitted for permanent residence at the time of application; trainees must have been lawfully admitted for permanent residence at the time of appointment. This must be documented by the individual's possession of an alien registration receipt card I-151 or I-551.

(2) See appendix 2 in regard to construction grants.

(3) This listing may be obtained from the State Liaison Officers designated by their respective States to administer this program or from the Advisory Council on Historic Preservation, 1522 K Street NW, Washington, DC 20005.

(4) See also appendix 2 in regard to construction grants.

(5) Copies may be obtained from the American National Standards Institute, Inc., 11 West 42nd Street, New York, NY 10036.

(6) These guidelines may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, MD 20892.