PART 50—POLICIES OF GENERAL APPLICABILITY

Subpart A (Reserved)

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

§ 50.201 Applicability.
The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.
As used in this subpart:
Arrange for means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.
Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.
Institutionalized individual means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for

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AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); Sec. 1006, Public Health Service Act, 84 Stat. 1507 (42 U.S.C. 300a-4), unless otherwise noted.

SOURCE: 43 FR 52165, Nov. 8, 1978, unless otherwise noted.
§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and §50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

1. Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled;

2. A description of available alternative methods of family planning and birth control;

3. Advice that the sterilization procedure is considered to be irreversible;

4. A thorough explanation of the specific sterilization procedure to be performed;

5. A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

6. A full description of the benefits or advantages that may be expected as a result of the sterilization;

7. Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in §50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.
§ 50.205 Consent form requirements.

(a) Required consent form. The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) Required signatures. The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) Required certifications. (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter’s knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any
hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

1. The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and

2. The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

i. The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

i. That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.


The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

APPENDIX TO SUBPART B OF PART 50--REQUIRED CONSENT FORM

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from __________________________ (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits
from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a . The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on (day), (month), (year).

I, , hereby consent of my own free will to be sterilized by a method called . My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or
Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature ____________________________ (Month, day, year)

You are requested to supply the following information, but it is not required:

Ethnicity and Race Designation

Ethnicity:
☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (mark one or more):
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed;

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

☐ Premature delivery

Individual's expected date of delivery: _____

☐ Emergency abdominal surgery:

(Describe circumstances): ______

Physician ______________________

Date _______________________

Paperwork Reduction Act Statement

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays the currently valid OMB control number. Public reporting burden for this collection of information will vary; however, we estimate an average of one hour per response, including for reviewing instructions, gathering and maintaining the necessary data, and disclosing the information. Send any comment regarding the burden estimate or any other aspect of this collection of information to the OS Reports Clearance Officer, ASBTF/Budget Room 503 HHH Building, 200 Independence Avenue, SW., Washington, DC 20201.

Respondents should be informed that the collection of information requested on this form is authorized by 42 CFR part 50, subpart B, relating to the sterilization of persons in federally assisted public health programs. The purpose of requesting this information is to ensure that individuals requesting sterilization receive information regarding the risks, benefits and consequences, and to assure the voluntary and informed consent of all persons undergoing sterilization procedures in federally assisted public health programs. Although not required, respondents are requested to supply information on their race and ethnicity. Failure to provide the other information requested on this consent form, and to sign this consent form, may result in an inability to receive sterilization procedures funded through federally assisted public health programs.

All information as to personal facts and circumstances obtained through this form will be held confidential, and not disclosed without the individual's consent, pursuant to any applicable confidentiality regulations.


Subpart C— Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

Authority: Sec. 118, Pub. L. 96-96, Oct. 12, 1979, unless otherwise noted.

Source: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

§ 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

§ 50.302 Definitions.

As used in this subpart: (a) Law enforcement agency means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) Medical procedures performed upon a victim of rape or incest means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) Physician means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) Public health service means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A rural health clinic, as defined under section 1(d)(aa)(2) of Pub. L. 95-
$50.303  
210, 91 Stat. 1465; except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§50.303  General rule.
Federal financial participation is not available for the performance of an abortion in programs or projects to which this subpart applies except under circumstances described in §50.304 or §50.306.


§50.304  Life of the mother would be endangered.
Federal financial participation is available in expenditures for an abortion when a physician has found, and so certified in writing to the program or project, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.


[43 FR 13868, July 21, 1978]

§50.305  [Reserved]

§50.306  Rape and incest.
Federal financial participation is available in expenditures for medical procedures performed upon a victim of rape or incest if the program or project has received signed documentation from a law enforcement agency or public health service stating:
(a) That the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;
(b) The date on which the incident occurred;
(c) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred;
(d) The name and address of the victim and the name and address of the person making the report (if different from the victim); and
(e) That the report included the signature of the person who reported the incident.

Federal financial participation is also available in expenditures for abortions for victims of rape or incest under the circumstances described in §50.304 without regard to the requirements of the preceding sentence.


§50.307  Documentation needed by programs or projects.
Federal financial participation is unavailable for the performance of abortions or other medical procedures otherwise provided for under §§50.304 and 50.306 if the program or project has paid without first having received the certifications and documentation specified in those sections.


§50.308  Drugs and devices and termination of ectopic pregnancies.
Federal financial participation is available with respect to the cost of drugs or devices to prevent implantation of the fertilized ovum, and for medical procedures necessary for the termination of an ectopic pregnancy.

§50.309  Recordkeeping requirements.
Programs or projects to which this subpart applies must maintain copies of the certifications and documentation specified in §§50.304 and 50.306 for three years pursuant to the retention and custodial requirements for records at 45 CF R 74.20 et seq.


§50.310  Confidentiality.
Information in the records or in the possession of programs or projects which is acquired in connection with the requirements of this subpart may not be disclosed in a form which permits the identification of an individual without the individual’s consent except as may be necessary for the health of the individual or as may be necessary for the Secretary to monitor the activities of those programs or projects. In any event, any disclosure shall be subject to appropriate safeguards.
§ 50.404 What disputes are covered by these procedures?

(a) These procedures are applicable to the following adverse determinations under discretionary project grants and cooperative agreements (both referred to in this subpart as grants) issued by the agencies identified at § 50.402:

(1) Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.

(2) A determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.

(3) A determination that a grant is void.

(4) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.

(b) A determination subject to this subpart may not be reviewed by the review committee described in § 50.405 unless an officer or employee of the agency has notified the grantee in writing of the adverse determination. The notification must set forth the reasons for the determination in sufficient detail to enable the grantee to respond and must inform the grantee of the opportunity for review under this subpart.

§ 50.405 What is the structure of review committees?

The head of the agency, or his or her designee, shall appoint review committees to review adverse determinations made by officials for programs under their jurisdiction. A minimum of three employees shall be appointed (one of whom shall be designated as chairperson) either on an ad hoc, case-by-case basis, or as regular members of review committees for such terms as may be designated. None of the members of the review committee reviewing any given appeal may be from the office of the responsible official whose adverse determination is being appealed (e.g., project officer, grants specialist, program manager, grants management officer).


§ 50.406 What are the steps in the process?

(a) A grantee with respect to whom an adverse determination described in §50.404(a) above has been made and who desires a review of that determination must submit a request for such review to the head of the appropriate agency or his or her designee no later than 30 days after the written notification of the determination is received, except that if the grantee shows good cause why an extension of time should be granted, the head of the appropriate agency or his or her designee may grant an extension of time.

(b) The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the grantee's position with respect to such issue(s) and the pertinent facts and reasons in support of the grantee's position. In addition to the required written statement, the grantee shall provide copies of any documents supporting its claim.

(c) When a request for review has been filed under this subpart with respect to an adverse determination, no action may be taken by the awarding agency pursuant to such determination until the request has been disposed of, except that the filing of the request shall not affect any authority which the agency may have to suspend assistance or otherwise to withhold or defer payments under the grant during proceedings under this subpart. This paragraph does not require the awarding agency to provide continuation funding during the appeal process to a grantee whose noncompeting continuation award has been denied.

(d) Upon receipt of a request for review, the head of the agency or his or her designee will make a decision as to whether the dispute is reviewable under this subpart and will promptly notify the grantee and the office responsible for the adverse determination of this decision. If the head of the agency or his or her designee determines that the dispute is reviewable, he or she will forward the matter to the review committee appointed under §50.405.

(e) The agency involved will provide the review committee appointed under §50.405 with copies of all relevant background materials (including applications(s), award(s), summary statement(s), and correspondence) and any additional pertinent information available. These materials must be tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(f) The grantee shall be given an opportunity to provide the review committee with additional statements and documentation not provided in the request for review described in paragraph (b) of this section. This additional submission, which must be organized and indexed as indicated under paragraph (e) of this section, should provide only material that is relevant to the review committee's deliberation of the issues in the case.

(g) The review committee may, at its discretion, invite the grantee and/or the agency staff to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

(h) Based on its review, the review committee will prepare a written decision to be signed by the chairperson and each of the other committee members. The review committee shall send the written decision with a transmittal letter to the grantee and shall send a copy of both to the official responsible for the adverse determination. If the
Public Health Service, HHS

§ 50.504 Allowable cost of drugs.

(a) The maximum amount which may be expended from program funds for the acquisition of any drug shall be the lowest of:

(1) The maximum allowable cost (MAC) of the drug, if any, established in accordance with 45 CFR part 19, plus a dispensing fee determined by the Secretary in accordance with paragraph (b) of this section, to be reasonable;

(2) The acquisition cost of the drug plus a dispensing fee determined by the Secretary, in accordance with paragraph (b) of this section, to be reasonable; or

(3) The provider’s usual and customary charge to the public for the drug; Provided, That the MAC established for any drug shall not apply to a brand of that drug prescribed for a patient which the prescriber has certified, in accordance with paragraph (c) of this section, is medically necessary for that patient; And Provided further, That where compensation for drug dispensing is included in other costs allowable under the applicable program statute and regulations, the terms and conditions of the grant or contract, and the applicable cost principles prescribed in 45 CFR part 74, no separate dispensing fee will be recognized.

[40 FR 34514, Aug. 15, 1975, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.503 Policy.

It is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible. In furtherance of this policy, the Secretary has established, in 45 CFR part 19, a procedure for determining the Maximum Allowable Cost for drugs which are purchased with program funds.

§ 50.502 Definitions.

As used in this subpart:

(a) Public Health Service means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, Food and Drug Administration, and all of their constituent agencies.

(b) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) Program funds means (1) Federal funds provided through grant or contract to support a program or project covered by §50.501, and (2) any non-Federal funds that are required as a condition of such grant or contract to be expended to carry out such program or project.

(d) Provider means one who furnishes medical or pharmaceutical services or supplies for which program funds may be expended under any of the programs or projects described in §50.501.

(e) Acquisition cost means the price generally and currently paid by providers for a drug marketed or sold by a particular formulator or labeler in the package size of drug most frequently purchased by providers, as determined by the Secretary on the basis of drug price information furnished by the Department.

[40 FR 34514, Aug. 15, 1975, as amended at 49 FR 38109, Sept. 27, 1984]

Subpart E—Maximum Allowable Cost for Drugs


SOURCE: 40 FR 34514, Aug. 15, 1975, unless otherwise noted.

§ 50.501 Applicability.

This subpart is applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service. It applies to Federal funds and to non-Federal funds which are required to be expended as a condition to receiving Federal funds under such programs or projects.

§ 50.502 Definitions.

As used in this subpart:

(a) Public Health Service means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, Food and Drug Administration, and all of their constituent agencies.

(b) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) Program funds means (1) Federal funds provided through grant or contract to support a program or project covered by §50.501, and (2) any non-Federal funds that are required as a condition of such grant or contract to be expended to carry out such program or project.

(d) Provider means one who furnishes medical or pharmaceutical services or supplies for which program funds may be expended under any of the programs or projects described in §50.501.

(e) Acquisition cost means the price generally and currently paid by providers for a drug marketed or sold by a particular formulator or labeler in the package size of drug most frequently purchased by providers, as determined by the Secretary on the basis of drug price information furnished by the Department.

[40 FR 34514, Aug. 15, 1975, as amended at 49 FR 38109, Sept. 27, 1984]
§ 50.601 Purpose.

This 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.

§ 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of this subpart by each Institution, to each Investigator participating in such research (see §50.604(a)); provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, “Investigator” includes the Investigator’s spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees...
or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

1. Salary, royalties, or other remuneration from the applicant institution;
2. Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
6. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102–564.

§ 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:
(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator’s reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution’s policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.
(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.
(c)(1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and
(ii) In entities whose financial interests would reasonably appear to be affected by the research.
(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.
(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
(g) Certify, in each application for the funding to which this subpart applies, that:
§ 50.605 Management of conflicting interests.

(a) The designated official(s) must:

(1) Review all financial disclosures; and

(2) Determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an institution may require the management of other conflicting financial interests, as the institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an investigator to comply with the conflict of interest policy of the institution has biased the design, conduct, or reporting of the PHS-funded research, the institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the institution for further action, which may include directions to the institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment...
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has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

§ 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure
45 CFR part 16—Procedures of the Departmental Grant Appeals Board
45 CFR part 74—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
45 CFR part 76—Government-wide debarment and suspension (non-procurement)
45 CFR part 79—Program Fraud Civil Remedies
45 CFR part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

PART 51—REQUIREMENTS APPLICABLE TO THE PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS PROGRAM

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§ 51.2 Definitions.

The provisions of this part apply to recipients of Federal assistance under the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended.

§ 51.1 Scope.

The provisions of this part apply to recipients of Federal assistance under the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended.

§ 51.2 Definitions.

In addition to the definitions in section 102 of the Act, as amended, the following definitions apply:

Abuse means any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to an individual with mental illness, and includes but is not limited to acts such as: rape or sexual assault; striking; the use of excessive force when placing an individual with mental illness in bodily restraints; the use of bodily or chemical restraints which is not in compliance with Federal and State laws and regulations; verbal, nonverbal, mental and emotional harassment; and any other practice which is likely to cause immediate physical or psychological harm or