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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.

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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the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes which include the ability to consent to sterilization.

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 and all of their constituent agencies.

The *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.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

[43 FR 52165, Nov. 8, 1978, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours

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have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 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; and

(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.

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

- (1) In labor or childbirth;
- (2) Seeking to obtain or obtaining an abortion; or
- (3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 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. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(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

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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.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure

or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 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.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.210 Review of regulation.

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**

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

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

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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 _____ 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 _____

Date: _____
(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

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter _____
Date _____

STATE OF PERSON OBTAINING CONSENT

Before _____ (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

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 appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent _____
Date _____
Facility _____
Address _____

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon _____ (name of individual to be sterilized), on _____ (date of sterilization), _____ (operation), I explained to him/her the nature of the sterilization operation _____ (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

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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 re-

sult 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.

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993; 68 FR 12308, Mar. 14, 2003]

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

AUTHORITY: Sec. 118, Pub. L. 96–86, 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–

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210, 91 Stat. 1485; 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.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 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.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[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.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 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.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 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 CFR 74.20 *et seq.*

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 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

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which will minimize the likelihood of disclosures of personal information in identifiable form.

Subpart D—Public Health Service Grant Appeals Procedure

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); 45 CFR 16.3(c).

SOURCE: 54 FR 34770, Aug. 22, 1989, unless otherwise noted.

§ 50.401 What is the purpose of this subpart?

This subpart establishes an informal procedure for the resolution of certain postaward grant and cooperative agreement disputes within the agencies and offices identified in § 50.402.

[63 FR 66062, Dec. 1, 1998]

§ 50.402 To what program do these regulations apply?

This subpart applies to all grant and cooperative agreement programs, except block grants, which are administered by the National Institutes of Health; The Centers for Disease Control and Prevention; the Agency for Toxic Substances and Disease Registry; the Food and Drug Administration; and the Office of Public Health and Science. For purposes of this subpart, these entities are hereinafter referred to as “agencies.”

[70 FR 76175, Dec. 23, 2005]

§ 50.403 What is the policy basis for these procedures?

The Secretary of Health and Human Services has established a Departmental Appeals Board for the purpose of providing a fair and flexible process for the appeal of written final decisions involving certain grant and cooperative agreement programs administered by constituent agencies of the Department. The regulatory provision which establishes the circumstances under which the Board will accept an appeal (45 CFR 16.3) provides, among other things, that the appellant must have exhausted any preliminary appeal process required by regulation before a formal appeal to the Departmental Board will be allowed. This subpart provides such an informal preliminary

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procedure for resolution of disputes in order to preclude submission of cases to the Departmental Appeals Board before an agency identified in § 50.402 has had an opportunity to review decisions of its officials and to settle disputes with grantees.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]

§ 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.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]

§ 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).

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]

§ 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 assist-

ance 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

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decision is adverse to the grantee's position, the transmittal letter must state the grantee's right to appeal to the Departmental Appeals Board under 45 CFR part 16.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66063, Dec. 1, 1998]

Subpart E—Maximum Allowable Cost for Drugs

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216).

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

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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]

§ 50.503 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.

§ 50.504 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.

(b) In determining whether a dispensing fee is reasonable, the Secretary will take into account:

(1) Cost components such as overhead, professional services, and profits,

(2) Payment practices of third-party payment organizations, including other Federal programs such as titles XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in the particular area.

(c) A certification by a prescriber, pursuant to paragraph (a) of this section, that a brand of drug is medically necessary for a particular patient shall be in the prescriber's own handwriting, in such form and manner as the Secretary may prescribe. An example of an acceptable certification is the notation "brand necessary". A procedure for checking a box on a form will not constitute an acceptable certification.

Subpart F—Promoting Objectivity in Research

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-4; Sec. 219, Tit. II, Div. D, Pub. L. 111-117, 123 Stat. 3034.

SOURCE: 76 FR 53283, August 25, 2011, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

§ 50.602 Applicability.

This subpart is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications. In those

few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

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) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

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, study or experiment 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 (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the In-

vestigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy

will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology

Transfer (STTR) Program, which was established by Public Law 102-564.

§ 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

Each Institution shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this subpart (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this subpart.

(b) Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to an Institution; or

(3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent

with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(f) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that

the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to § 50.605(a).

(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to § 50.605(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k) Certify, in each application for funding to which this subpart applies, that the Institution:

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this subpart.

§ 50.605 Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii)(A) In addition, whenever a financial conflict of interest is not identi-

fied or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken

to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

(4) Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)(i) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial

interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this subpart that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the PHS Awarding

Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- (viii) A description of the key elements of the Institution's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

(5) In addition to the types of financial conflicts of interest as defined in this subpart that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall 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 PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

(b) The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any

Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interest. An Institution is required to submit, or permit on site review of, 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 or other information that may be available, the PHS Awarding Component may decide that a particular financial 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 the financial conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, 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 has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

§ 50.607 Other HHS regulations that apply.

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

- 2 CFR part 376—Nonprocurement debarment and suspension (HHS)
- 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
- 45 CFR part 79—Program fraud civil remedies
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments

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

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AUTHORITY: 42 U.S.C. 10801, *et seq.*

SOURCE: 62 FR 53564, Oct. 15, 1997, unless otherwise noted.

§ 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 result in long-term harm if such practices continue.

Act means the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended, also referred to as Protection and Advocacy for Individuals with Mental Illness Act.

ADD means the Administration on Developmental Disabilities within the Administration for Children and Families, Department of Health and Human Services.

Care or Treatment means services provided to prevent, identify, reduce or stabilize mental illness or emotional impairment such as mental health screening, evaluation, counseling, biomedical, behavioral and psychotherapies, supportive or other