CONFlicts of interest
“rules and regUlations” summary

jeffrey s. ankrom, j.d., presenter (jankrom@indiana.edu)
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disclaimer: This is not a complete set of the laws or regulations that researchers may be required
to follow. “Rules and regs” are always subject to modification. Still, these texts may help the
reader understand how conflict-of-interest laws and regulations function.
nothing in these materials or the related presentation is legal advice. For help with
specific legal issues, consult an attorney conversant with the subject matter and admitted to
practice in the relevant jurisdiction(s). Be frank about your concerns.

Federal Register (FR). The Federal Register is a compendium of a great variety of documents,
including speeches in Congress, executive orders, proposed rules, and final rules (which
will in turn be included in the Code of Federal Regulations).
• A citation that reads “60 FR 35820” or “60 Fed. Reg. 35820” means “Volume 60 (= 1995) of the Federal Register, page 35820.”
• Many Federal Register documents can be retrieved at www.federalregister.gov
  (using the “search by citation” link). There is also the site of the Government Printing Office: www.gpoaccess.gov . Here, searching is easier if you know the
  volume number, the date, and the government entity involved. When in doubt, Google.

developed by various government departments, agencies, institutes, and other entities to
implement the requirements of legislation. (Thus, if Congress authorizes a government
office to charge user fees, regulations will be created to specify the amounts of the fees,
how they are to be collected, and so forth.)
• A citation that reads “45 CFR § 94.1-6” means “Code of Federal Regulations, Title 45, Part [= Section] 94.1-6.”
• Provisions of the Code of Federal Regulations are posted by the Government Printing Office at www.gpoaccess.gov/cfr/ . Updates are done section-by-section through the
  year. Start your search with the current year; if this year’s version of desired section
  is not yet available, search under last year.

United States Code (USC). Includes all federal legislation that remains in effect (or is scheduled
to enter into effect in the future). (Legislation often includes changes be made is a
variety of places in the USC. To see a copy of the legislation itself, go to the CFR. To see
the law that is now in force, go to the USC.)
• A citation written “35 USC § 200” or “35 U.S.C. 200” or some variation thereof
  means “United States Code, Title 35, Section 200.”
• Provisions of the United States Code can be retrieved from www.gpoaccess.gov/usc/ . If the desired title is not available, search under the previous year.

Retrieving court decisions is a more complicated matter. Try Google. It often works, especially
for well-known cases.
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Department of Health and Human Services (HHS).
Citation: 45 CFR § 94.1-6 (as amended in 76 FR 53288-53293, August 25, 2011, HHS, described in Item B, below).

Code of Federal Regulations
Title 45. Public Welfare
Subtitle A. Department of Health and Human Services
Subchapter A. General Administration
Part 94. Responsible Prospective Contractors.

[10 pages, with printed numbers 468-477]

(A copy is provided, current as of October 1, 2011:
http://www.gpoaccess.gov/cfr/. Select the most recent year. If Title 45 does not yet appear for that year, check the previous year. Or Google.)

PART 94—RESPONSIBLE PROSPECTIVE CONTRACTORS

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§ 94.1 Purpose.

This part promotes objectivity in research by establishing standards that provide reasonable assurance that the design, conduct, and reporting of research performed under PHS contracts will be free from bias resulting from investigator financial conflicts of interest.

§ 94.2 Applicability.

This part is applicable to each Institution that submits a proposal, or that receives, Public Health Service (PHS) research funding by means of a contract and, through the implementation of this part by the Institution, to each investigator who is planning to participate in, or is participating in such research: provided, however, that this part does not apply to SBIR Program Phase I applications.

§ 94.3 Definitions.

As used in this part:

Contractor means an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

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 submits a proposal, 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, data 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.

Key personnel includes the PD/PI and any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.242-70 and identified as key personnel in the contract proposal and contract.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to 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 key personnel and investigator under this part.

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 part.

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 part, the term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, whether authorized under the PHS Act or other statutory authority.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’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), as determined through reference to public prices or other reasonable measures of fair market value;

(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.
§ 94.4 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 part, 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 part (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 part.

(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 contract 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 part 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.
2. 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 part. 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.
3. 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 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 part.
4. Additionally, 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
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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 part.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, 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 date of submission of the Institution’s proposal 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 (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 part 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 mitigation report pursuant to §94.5(a).

(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to §94.5(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 of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.

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

(k) Certify, in each contract proposal to which this part 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 research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with this part’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 part;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of significant 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 part.

§ 94.5 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 §94.4(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:

(1) 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
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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 identified 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 noncompliance, 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 noncompliance, 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 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 part. 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 part, 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 key personnel as defined in this part:

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and
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(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 that was not previously disclosed, or upon the disclosure of a significant financial interest 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 part 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 part. 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 part. 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,
§ 94.6 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, an Institution shall promptly notify the PHS Awarding Component of the corrective action 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/Contract 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-$1,999; $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 an annual FCOI report to the PHS Awarding Component 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 part 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.
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.

(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 of, and response to, such disclosure, regardless of whether or not 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 part. 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 part. The PHS Awarding Component may determine that issuance of a Stop Work Order by the Contracting Officer or other enforcement action 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 part, 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.

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95.612 Disallowance of Federal Financial Participation (FFP).
“Rules and Regs” Item B. Link only: long document.

Department of Health and Human Services (HHS).
Citation: 76 FR 53526-53293, August 25, 2011 (38 pages).
This final rule modifies conflict of interest regulation at the Department of Health and Human Services and the Public Health Service:
   Pages 53283-53288 modify 42 CFR 50 (re Public Health Service)—
      including Item E, below.
   Pages 53288-53293 modify 45 CFR 94 (re Health and Human Services)—
      Item A, above.
Final Rule: “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”
[38 pages, with printed numbers 53526-53293.]
This Federal Register document is available online through
“Rules and Regs” Item C.

Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP).

Department of Health and Human Services

Final Guidance Document

Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

This document replaces the “HHS Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection” dated January 10, 2001. This document is intended to provide guidance. It does not create or confer rights for or on any person and does not operate to bind the Department of Health and Human Services (HHS, or the Department), including the Food and Drug Administration (FDA), or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. Introduction

A. Purpose

In this guidance document, HHS raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by HHS or regulated by the FDA. The consideration of financial relationships, as discussed in this document relates to human subject protection in research conducted under the HHS or FDA regulations (45 CFR part 46, 21 CFR parts 50, 56).

1. Under the Public Health Service Act and other applicable law, HHS has authority to regulate institutions engaged in HHS conducted or supported research involving human subjects. For a description of what is meant by institutions engaged in research see the Office for Human Research Protections (OHRP) engagement policy at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm. Under the Federal Food, Drug, and Cosmetic Act, FDA has the authority to regulate Institutional Review Boards (IRBs) and investigators involved in the review or conduct of FDA-regulated research.

This document does not address HHS Public Health Service regulatory requirements that cover institutional management of the financial interests of individual investigators who conduct Public Health Service (PHS) supported research (42 CFR part 50, subpart F, and 45 CFR part 94). This document also does not address FDA regulatory requirements that place responsibilities on sponsors to disclose certain financial interests of investigators to FDA in marketing applications (21 CFR part 54). Guidelines interpreting the application of the PHS regulations to research conducted or supported by the National Institutes of Health (NIH) that involve human subjects are available at http://era.nih.gov/services_for_applicants/other/coi.cfm. Guidance interpreting the provisions of the FDA regulations appears at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm.

The PHS regulations require grantee institutions and contractors to designate one or more persons to review investigators' financial disclosure statement describing their significant financial interests and ensure that conflicting financial interests are managed, reduced, or eliminated before expenditure of funds (42 CFR 50.604(b), 45 CFR 94.4(b)). The PHS threshold for significant financial interest is $10,000 per year income or equity interests over $10,000 and 5 percent ownership in a company (42 CFR 50.603, 45 CFR 94.3). The regulations give several examples of methods for managing investigators' financial conflicts of interest (42 CFR 50.605(a), 54 CFR 94.5(a)). Sponsors are required to disclose certain financial interests of clinical investigators to FDA in marketing...
This document is nonbinding and does not change any existing regulations or requirements, and does not impose any new requirements.

Institutions and individuals involved in human subjects research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property rights. A financial interest related to a research study may be a conflicting financial interest. The Department recognizes that some conflicting financial interests in research may affect the rights and welfare of human subjects. This document provides some possible approaches to consider in assuring that human subjects are adequately protected. Institutional review boards (IRBs), institutions, and investigators engaged in human subjects research each have appropriate roles in ensuring that financial interests do not compromise the protection of research subjects.\(^3\)

B. Target Audiences

The principal target audiences include investigators, IRB members and staffs, institutions engaged in human subjects research and their officials, and other interested members of the research community.

C. Underlying Principles

The regulations protecting human research subjects are based on the ethical principles described in the Belmont report:\(^4\) respect for persons, beneficence, and justice. The Belmont principles should not be compromised by financial relationships. Openness and honesty are indicators of respect for persons, characteristics that promote ethical research and can only strengthen the research process.

D. Basis for This Document

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approval applications under the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 CFR part 54). FDA regulations at 21 CFR part 54 address requirements for the disclosure of certain financial interests held by clinical investigators. The purpose of these regulations is to provide additional information to allow FDA to assess the reliability of the clinical data (21 CFR 54.1). The FDA regulations require sponsors seeking marketing approval for products to certify that investigators do not have certain financial interests, or to disclose those interests to FDA (21 CFR 54.4). These regulations require sponsors to report (1) financial arrangements between the sponsor and the investigator whereby the value of the investigator's compensation could be influenced by the outcome of the trial, (2) any proprietary interest in the product studied held by the investigator; (3) significant payments of other sorts over $25,000 beyond costs of the study; or (4) any significant equity interest in the sponsor of a covered study (21 CFR 54.4).

Note that when the PHS regulations were promulgated, the National Science Foundation (NSF) Investigator Financial Disclosure Policy was revised to match closely the PHS regulations. The NSF conflict of interest policy appears at [http://www.gpo.gov/fdsys/pkg/FR-1995-07-11/html/95-16800.htm](http://www.gpo.gov/fdsys/pkg/FR-1995-07-11/html/95-16800.htm).

\(^3\) The Department recognizes that some non-financial conflicting interests related to research also may affect the rights and welfare of human subjects. However, non-financial interests are beyond the scope of this guidance document.

\(^4\) [http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm)
The HHS human subject protection regulations (45 CFR part 46) require that institutions performing HHS conducted or supported non-exempt research involving human subjects have the research reviewed and approved by an IRB whose goal is to help ensure that the rights and welfare of human subjects are protected. The comparable FDA regulations (21 CFR parts 50 and 56) require that FDA regulated research involving human subjects is reviewed and approved by such an IRB. Under these regulations, IRBs are responsible for, among other things, determining that:

- Risks to subjects are minimized (45 CFR 46.111(a)(1), 21 CFR 56.111(a)(1));
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects (45 CFR 46.111(a)(2), 21 CFR 56.111(a)(2));
- Selection of subjects is equitable (45 CFR 46.111(a)(3), 21 CFR 56.111(a)(3));
- Informed consent will be sought from each prospective subject (45 CFR 46.111(a)(4), 21 CFR 56.111(a)(4)); and,
- The possibility of coercion or undue influence is minimized (45 CFR 46.116, 21 CFR 50.20).

In addition the IRB may

- Require that additional information be given to subjects “when in the IRB's judgment the information would meaningfully add to protection of the rights and welfare of subjects” (45 CFR 46.109(b), 21 CFR 56.109(b)).

For HHS conducted or supported research, the funding agency may impose additional conditions as necessary for the protection of human subjects (45 CFR 46.124).

IRBs are also responsible for ensuring that members who review research have no conflicting interest. 45 CFR 46.107(e) directly addresses conflicts of interest by requiring that “no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.” FDA regulations include identical language at 21 CFR 56.107(e).

Concerns have grown that financial conflicts of interest in research, derived from financial relationships and the financial interests they create, may affect the rights and welfare of human subjects in research. Financial interests are not prohibited, and not all financial interests cause conflicts of interest or affect the rights and welfare of human subjects. HHS recognizes the complexity of the relationships between government, academia, industry and others, and recognizes that these relationships often legitimately include financial relationships. However, to the extent financial interests may affect the rights and welfare of human subjects in research, IRBs, institutions, and investigators need to consider what actions regarding financial interests may be necessary to protect those subjects.
In May 2000, HHS announced five initiatives to strengthen human subject protection in clinical research. One of these was to develop guidance on financial conflict of interest that would serve to further protect research participants. As part of this initiative, HHS held a conference on the topic of human subject protection and financial conflict of interest on August 15-16, 2000. A draft interim guidance document, “Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection,” based on information obtained at and subsequent to that conference was made available to the public for comment on January 10, 2001. This document replaces that draft interim guidance. The Department notes that other organizations have also addressed financial interests in human research via reports, guidance and recommendations. Many of these contain strong and sound ideas for actions to deal with


6 Recent Federal and Private Sector Activities: In addition to the HHS initiative, several Federal organizations have examined the issues related to financial relationships in human subjects research:

* The National Bioethics Advisory Commission (NBAC), in a comprehensive examination of the “Ethical and Policy Issues in Research Involving Human Participants,” in Chapter 3 recommended development of federal, institutional, and sponsor policies and guidance to ensure that research subjects' rights and welfare are protected from the effects of conflicts of interest (http://www.georgetown.edu/research/nrcri/nbac/human/overvol1.pdf).
* The HHS Office of the Inspector General (OIG) has issued a series of reports examining regulation and activities of IRBs. A June 2000 OIG report addressed recruitment practices and found that about one-quarter of the surveyed IRBs consider financial arrangements with sponsors of research as part of their protocol review (http://oig.hhs.gov/oei/reports/oei-01-97-00195.pdf).
* In December 2001, the General Accounting Office released report 02-89 “Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest.” The report recommended that the Secretary of Health and Human Services develop specific guidance or regulations concerning institutional financial conflicts of interest (http://www.gao.gov/).
* Two accrediting bodies for human subject protection programs have included elements addressing individual and institutional conflicts of interest in their accreditation evaluations, the Association for the Accreditation of Human Research Protection Programs (http://www.aahrpp.org/images/Evaluation_Instrument_1.pdf) and the National Committee for Quality Assurance, (http://www.ncqa.org/Programs/QSG/VAHRPAP/VAHRPAPfindstds.pdf).
Internationally, the World Medical Association's revision in 2000 of the Declaration of Helsinki,
potential financial conflicts of interest on the part of institutions, investigators and IRBs.

II. Guidance for Institutions, IRBs and Investigators

A. General Approaches to Address Financial Relationships and Interests in Research Involving Human Subjects

The Department recommends that in particular, IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. These entities may find it useful to include the following questions in their deliberations:

- What financial relationships and resulting financial interests could cause potential or actual conflicts of interest?
- At what levels should those potential or actual financial conflicts of interest be managed or eliminated?
- What procedures would be helpful, including those to
  • collect and evaluate information regarding financial relationships related to research,
  • determine whether those relationships potentially cause a conflict of interest, and
  • determine what actions are necessary to protect human subjects and ensure that those actions are taken?
- Who should be educated regarding financial conflict of interest issues and policies?
- What entity or entities would examine individual and/or institutional financial relationships and interests?

B. Points for Consideration

Financial interests determined to create a conflict of interest may be managed by eliminating them or mitigating their impact. A variety of methods or combinations of methods may be effective. Some methods may be implemented by institutions engaged in the conduct of research, and some methods may be implemented by IRBs or investigators. Some of those may apply before research begins, and some may apply during the conduct of the research.

In establishing and implementing methods to protect the rights and welfare of human subjects from conflicts of interest created by financial relationships of parties involved in research, the Department recommends that IRBs, institutions engaged in research, and investigators consider

(http://www.wma.net/e/policv/17-c_e.html) principle 22, includes “sources of funding” among the items of information to be provided to subjects. A number of individual institutions also have developed policies for their own situations, as noted in the NIH Guide Notice issued in June 2000 (http://grants.nih.gov/guide/notice-files/NOT-OD-00-040.html). Some of these policies involve conflicts of interest management methods and address institutional financial interests as well as individual interests.
the questions below. Additional questions may be appropriate. The Department's intent is not to be exhaustive, but to suggest ways to examine the issues so that appropriate actions can be taken to protect the rights and welfare of human research subjects. The Department recognizes that a number of institutions currently address such issues in their consideration of financial interests of parties involved in human subject research.

- Does the research involve financial relationships that could create potential or actual conflicts of interest?
  - How is the research supported or financed?
  - Where and by whom was the study designed?
  - Where and by whom will the resulting data be analyzed?

- What interests are created by the financial relationships involved in the situation?
  - Do individuals or institutions receive any compensation that may be affected by the study outcome?
  - Do individuals or institutions involved in the research:
    -- have any proprietary interests in the product, including patents, trademarks, copyrights, or licensing agreements?
    -- have an equity interest in the research sponsor and, if so, is the sponsor a publicly held company or non-publicly held company?
    -- receive significant payments of other sorts? (e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, or honoraria)
    -- receive payment per participant or incentive payments, and are those payments reasonable?

- Given the financial relationships involved, is the institution an appropriate site for the research?

- How should financial relationships that potentially create a conflict of interest be managed?

- Would the rights and welfare of human subjects be better protected by any or a combination of the following:
  - reduction of the financial interest?
  - disclosure of the financial interest to prospective subjects?
  - separation of responsibilities for financial decisions and research decisions?
  - additional oversight or monitoring of the research?
  - an independent data and safety monitoring committee or similar monitoring body?
  - modification of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change of investigator?
  - elimination of the financial interest?

C. Specific Points for Consideration

1. Institutions
The Department recommends that institutions engaged in HHS conducted or supported human subjects research consider whether the following actions or other actions would help ensure that financial interests do not compromise the rights and welfare of human research subjects.

Actions to consider:

- Establishing the independence of institutional responsibility for research activities from the management of the institution’s financial interests.

- Establishing conflict of interest committees (COICs) or identifying other bodies or persons and procedures to
  - deal with individuals' or institutional financial interests in research or verify the absence of such interests and
  - address institutional financial interests in research.

- Establishing criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.

- Establishing clear channels of communication between COICs and IRBs.

- Establishing policies on providing information, recommendations, or findings from COIC deliberations to IRBs.

- Establishing measures to foster the independence of IRBs and COICs.

- Determining whether particular individuals should report financial interests to the COIC. These individuals could include IRB members and staff and appropriate officials of the institution, along with investigators, among those who report financial interests to COICs.

- Establishing procedures for disclosure of institutional financial relationships to COICs.

- Providing training to appropriate individuals regarding financial interest requirements.

- Using independent organizations to hold or administer the institution's financial interest.

- Including individuals from outside the institution in the review and oversight of financial interests in research.

- Establishing policies regarding the types of financial relationships that may be held by parties involved in the research and circumstances under which those financial relationships and interests may or may not be held.

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7 The acronym COIC will be used to represent the body or person(s) designated to review financial interests.
2. IRB Operations

The Department recommends that institutions engaged in human subjects research and IRBs that review HHS conducted or supported human subjects research or FDA regulated human subjects research consider whether establishing policies and procedures addressing IRB member potential and actual conflicts of interest as part of overall IRB policies and procedures would help ensure that financial interests do not compromise the rights and welfare of human research subjects. As noted, 45 CFR 46.107(e) and 21 CFR 56.107(e) prohibit an IRB member with a conflicting interest in a project from participating in the IRB’s initial or continuing review, except to provide information as requested by the IRB.

Policies and procedures to consider:

- Reminding members of conflict of interest policies at each meeting and documenting any actions taken regarding IRB member conflicts of interest related to particular protocols.
- Developing educational materials for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects research.

3. IRB Review

The Department recommends that IRBs reviewing HHS conducted or supported human subjects research or FDA regulated human subjects research consider whether the following actions, or other actions related to conduct or oversight of research, would help ensure that financial interests do not compromise the rights and welfare of human research subjects.

Actions to consider:

- Determining whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.
- Determining whether other actions are necessary to minimize risks to subjects.
- Determining the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

4. Investigators

The Department recommends that investigators conducting human subjects research consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects, and what actions to take.

Actions to consider:
• Including information in the informed consent document, such as
  • the source of funding and funding arrangements for the conduct and review of research, or
  • information about a financial arrangement of an institution or an investigator and how it is being managed.

• Using special measures to modify the informed consent process when a potential or actual financial conflict exists, such as
  • having another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.
  • Using independent monitoring of the research.

Dated: /May 5, 2004/

Tommy G. Thompson
Secretary
Department of Health and Human Services.
“Rules and Regs” Item D. Link only: rules still under consideration.

The Department of Health and Human Services, Centers for Medicare and Medicaid Services has released proposed rules (76 FR 78742-78773, December 19, 2011):

“Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests.”

The proposed rules—designed to implement part of the Affordable Care Act—would modify 42 CFR Parts 402-403.

[32 pages, with printed page numbers 78742-78773.]

“Rules and Regs” Item E.

Public Health Service (PHS).
Citation: 42 CFR §§ 50.601-607 (as amended in 76 FR 53283-53288, Aug. 25, 2011, herewith as “Rules and Regs” Item B, which includes additional pages)
Code of Federal Regulations
Title 42. Public Health
Chapter 1. Public Health Service, Department of Health and Human Services
Subchapter D. Grants
Part 50. Policies of General Applicability
Subpart F. Promoting Objectivity in Research
[10 pages, with printed numbers 196-205]
(A copy is provided, current as of October 1, 2011; http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part50-subpartF.pdf. To check for more recent versions, go to http://www.gpoaccess.gov/cfr/. Select the most recent year. If Title 42 does not yet appear for that year, check the previous year.)

§50.601

(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


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

§50.602 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.

§50.603 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.
Public Health Service, HHS

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 investigator’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
§ 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.
§ 50.604

(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.

(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 periods for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time periods shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS Awarding Component.

(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.

(ii) Alternatively, if the subrecipient’s Investigators must comply with the PHS-funded research, and disclose to the awardee Institution for disclosing significant financial interests that are directly related to the awardee Institution: the subrecipient’s work for the awardee Institution.

(iii) Additionally, if the subrecipient’s Investigators must comply with the subrecipient’s financial conflicts of interest policy, the agreement referenced above shall specify time periods for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time periods shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS Awarding Component.

(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
§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 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.

(b) 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:
(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) In addition, whenever a financial conflict of interest is not identified 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)(9)(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
§ 50.606

(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
“Rules and Regs” Item F.

National Science Foundation (NSF).
Citation: 45 CFR § 680.
Code of Federal Regulations
Title 45. Public Welfare
Subtitle B. Regulations Relating to Public Welfare
Chapter VI. National Science Foundation

Part 680. National Science Foundation Rules of Practice
[Concerns conflicts of interest of NSF employees.]
[3 pages, with printed numbers 226-228]

(A copy is provided, current as of October 1, 2011:
http://www.gpoaccess.gov/cfr/. Select the most recent year. If Title 45
does not yet appear for that year, check the previous year.)

Note: Other policies governing employees of the National Science Foundation
can be found at http://www.nsf.gov/policies/conflicts.jsp. Employees are
directed to “NSF Manual 15: Conflicts of Interest and Standards of Ethical
Conduct,” which can be accessed at

These policies should not be confused with the rules governing institutions and
researchers participating in NSF-supported research.
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PART 680—NATIONAL SCIENCE FOUNDATION RULES OF PRACTICE

Subpart A—Rules of Practice for the National Science Foundation

Sec. 680.10 Definitions: cross-references to employee ethical conduct standards and financial disclosure regulations.

(a) Definitions. Under this subpart, unless a provision plainly indicates otherwise:

(1) Award means any grant, contract, cooperative agreement, loan, or other arrangement made by the Government.

(2) Employee includes, in addition to any individual defined in 5 CFR 2635.102(h), any individual working at NSF under the Intergovernmental Personnel Act. It includes any part-time or intermittent employee, temporary consultant; but not a special Government employee, as defined in 18 U.S.C. 202(a).

(3) Institution means any university, college, business firm, research institute, professional society, or other organization. It includes all parts of a university or college, including all institutions in a multi-institution State or city system. It includes any university consortium or joint corporation; but not the universities that belong to such a consortium. Those universities shall be considered separate institutions for purposes of this part.

(4) Proposal means an application for an award and includes a bid.

(b) Cross-references to employee ethical conduct standards and financial disclosure regulations. Members of the National Science Board and other employees of the National Science Foundation (NSF), including special Government employees, should refer to the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635. The National Science Foundation’s regulations at 5 CFR part 5301 which supplement the executive branch Standards, and the executive branch financial disclosure regulations at 5 CFR part 2634.

§ 680.11 Staff involvement with NSF proposals and awards.

(a)(1) Many scientists, engineers, and educators interrupt active research and teaching careers to spend a year or two at NSF and then return to research and teaching, usually at the same institution from which they came. Many such visiting scientists, engineers, and educators (and a few permanent employees) who have been principal investigators under NSF awards before coming to NSF, retain some interest or association with the work. If an individual is a principal investigator under an NSF award, the individual is not precluded from retaining ties to the work after becoming an NSF employee. The employee may stay in contact with those who are continuing the work in the employee’s laboratory or on his or her project. The employee may continue to supervise graduate students. And the employee may visit and work in the laboratory on his or her own time for these and related purposes.

(2) Before a prospective employee comes to NSF, the prospective employee and the grantee institution must designate, subject to NSF approval, a “substitute principal investigator”—i.e., another scientist who will be responsible for the work and equipment and will represent the institution in any dealings with NSF officials while the prospective employee is at NSF.

(3) Appointment of a substitute principal investigator is unnecessary if all
work under an award is to be completely suspended while the employee is at NSF. If the work is to be suspended, the employee and the grantee institution must inform the NSF in writing before the employee's employment begins. Work under the award may be resumed when the employee completes his or her NSF employment, and its term may be extended to account for the time lost during the employee's NSF employment.

(b)(1) NSF will entertain no proposal on which a current NSF employee would be a senior investigator or equivalent, unless it is a proposal for continuation or extension of support for work on which the employee served in that capacity before coming to NSF. Any proposal for continuation of NSF support at essentially the same level (with reasonable allowance for inflation) will normally be considered a proposal for continuation or extension if it would support the work of the same investigator and his or her laboratory or group (if any) in the same general field of science, engineering, or education, notwithstanding that the focus of the work may change in response to research opportunities or educational needs.

(2) Someone other than the current NSF employee must submit any such proposal for continuation or extension of work NSF previously supported and handle all negotiations with NSF, but the capacity in which the current NSF employee will serve should be clearly spelled out in the proposal.

(c) In accordance with 5 CFR 5301.103(a)(1), an NSF employee may not receive, directly or indirectly, any salary, consulting fee, honorarium, or other form of compensation for services, or reimbursement of expenses, from an NSF award.

§680.12 One-year NSF post-employment restrictions.

(a) For one year after leaving NSF employment, a former NSF employee, including a special Government employee who has performed work for NSF on more than 60 days in the previous twelve months, shall not represent himself, herself, or any other person in dealings with any NSF official on any proposal, project, or other particular matter.

(b) The one-year restriction contained in paragraph (a) of this section is in addition to any post-employment restriction imposed by statute, including 18 U.S.C. 207 and 41 U.S.C. 423. To the extent that any disqualification required by paragraph (a) of this section is not also required by statute, written exceptions may be granted by the NSF's General Counsel, whose decisions shall be final. Exceptions will be rare and will be granted only where strict application of the rules would result in undue hardship for former short-term employees or for other former employees, and when granting an exception would not result in an unfair advantage to the former employee.

(c)(1) Paragraph (a) of this section applies to particular matters involving specific parties, such as grants, contracts, or other agreements; applications for permits, licenses, or the like; requests for rulings or similar official determinations; claims; investigations or audits; charges or accusations against individuals or firms; adjudicatory hearings; and court cases.

(2) For former employees, other than special Government employees, paragraph (a) of this section also applies to particular matters that do not involve specific parties, such as:

(i) Determinations to establish or dis-establish a particular program or set its budget level for a particular fiscal year;

(ii) Decisions to undertake or terminate a particular project;

(iii) Decisions to open or not open a contract to competitive bidding;

(iv) General policy or rulemaking—including, for example, decisions on particular NSF rules or formal policy, such as adoption or amendment of a resolution by the National Science Board, promulgation or amendment of an NSF regulation or circular, amendment of standard grant or contract terms, or changes to NSF manuals or policy documents; and

(v) Agency positions on particular legislative or regulatory proposals.

(d) Paragraph (a) of this section does not apply to:

(1) Any expression of a former employee's views on policy issues where
the circumstances make it obvious that the former employee is only speaking as an informed and interested citizen, not representing any financial or other interests of his or her own or of any other person or institution with which he or she is associated;

(2) Any appearance or communication concerning matters of a personal or individual nature, such as the former employee's taxes, salary, benefits, possible Federal employment, rights as a former employee, or the application of conflict-of-interest rules to something the former employee proposes to do;

(3) Any appearance on the former employee's own behalf in any litigation or administrative proceeding;

(4) Any presentation of scientific or technical information (at a site visit, for example) or any other communication of scientific or technical information on work being proposed or conducted.

(e) As soon as his or her NSF employment ceases, a former NSF employee (including any former special Government employee described in paragraph (a) of this section) may again be listed as principal investigator on an NSF award, may be listed as principal investigator in any proposal or award, and may sign a proposal as principal investigator. However, the former employee and the grantee institution shall formally designate, subject to NSF approval, a "substitute negotiator" who, though not principally responsible for the work, will represent the former employee and the institution in dealings with NSF officials on any proposal or project for as long as the former employee would be barred from representational contacts with NSF by paragraph (a) of this section or by statute.

§680.13 Purposes for "substitute" requirements.

Appointment of a "substitute principal investigator" or "substitute negotiator" ensures against unthinking violation of the restrictions on dealings with NSF officials. It serves this purpose by flagging proposals or awards affected by the restrictions and by identifying someone else with whom NSF officials can properly discuss them or negotiate over them. Designation of a substitute principal investigator while an employee is at NSF has two additional functions: it identifies another person to be responsible for the work and equipment, and it reminds all concerned that during an employee's NSF service his or her attentions should focus on NSF duties.

Subpart B (Reserved)

PART 681—PROGRAM FRAUD CIVIL REMEDIES ACT REGULATIONS

PURPOSE, DEFINITIONS, AND BASIS FOR LIABILITY

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681.2 Definitions.
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“Rules and Regs” Item G.

National Science Foundation (NSF).
Citation: 60 FR 35820, Notices—NSF, July 11, 1995
Code of Federal Regulations
Vol. 60, No. 132, Tuesday, July 11, 1995—Notices
Investigator Financial Disclosure Policy
[4 pages, with printed numbers 35820-35823]
Available at www.federalregister.gov or at

.
EFFECTIVE DATE: The effective date of the Policy in order to make the Policy more technical changes and clarifications to its Investigator Financial Disclosure Policy in order to make the Policy more consistent with the provisions of the final Department of Health and Human Services (HHS) rule on this subject.

EFFECTIVE DATES: Christopher L. Ashley, Assistant General Counsel, National Science Foundation, 4201 Wilson Boulevard, Room 1265, Arlington, VA 22230, (703) 306-1060.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Control Number 3145-0149

On June 28, 1994 NSF published in the Federal Register a final Policy announcing revised award conditions relating to investigator financial disclosure. Those revised conditions require grantee institutions to maintain written and enforced policies on investigator conflict of interest. 59 FR 33308 (June 28, 1994).

NSF has been coordinating its Investigator Financial Disclosure Policy with the Public Health Service and the Office of the Secretary of the Department of Health and Human Services (HHS). At the same time NSF published its final policy, HHS received a notice of proposed rulemaking also dealing with investigator conflicts. HHS received and reviewed public comments on that proposed rule, and is issuing in this Federal Register its final rule regarding investigator conflicts that will be effective on October 1, 1995. In cooperation with HHS, NSF is now making certain corresponding technical changes and clarifications to its Investigator Financial Disclosure Policy in order to maintain consistency with the final HHS rule. In addition, NSF and HHS will be working together to develop common guidance, including a set of questions and answers, to help institutions implement conflict of interest policies that comply with both HHS and NSF requirements.

The following summarizes the changes and clarifications to NSF's Investigator Financial Disclosure Policy:

Grant Policy Manual References: All references to GPM 310 will be changed to GPM 510.

Disclosures by Investigators:

Subparagraph b of GPM 510 will be revised to require disclosure to the institution's representative of significant financial interests that "would reasonably appear to be affected" by the activities funded or proposed for funding by NSF. Previously, the provision had required disclosure of interests that "reasonably appear to be directly and significantly affected" by such activities. This change will result in a slightly broader disclosure by the investigator. As explained below, the institutional representative(s) will be responsible for reviewing the disclosures to determine which disclosed interests could directly and significantly affect the design, conduct or reporting of the research.

Definition of "Significant Financial Interest"—Exclusions: For greater clarity, the exclusion set out in subparagraph b of GPM 510 will be split into two separate exclusions—one for equity interests and one for other types of payments. Also, the dollar threshold increased from $5,000 to $10,000. To be excluded from the definition of "significant financial interest," an equity interest, when aggregated for the investigator and his or her spouse and dependent children, must be under both the $10,000 and five percent ownership thresholds. For example, an investigator who owns an equity interest which is worth $20,000 (with reference to public prices or other reasonable measures of fair market value), but which represents only one percent ownership in the entity, would nevertheless be required to disclose that interest if it would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF.

Conflicts of Interest: In subparagraph d of GPM 510, the definition of a conflict of interest will be revised. As revised, a conflict of interest exists if the reviewer(s) of disclosures determines that a significant financial interest "could directly and significantly affect the design, conduct, or reporting of NSF-funded activities. Thus, contrary to the previous definition, the reviewer(s) rather than the investigator determines whether a significant financial interest directly and significantly affects the design, conduct or reporting of NSF-funded activities.

Timing of Conflict of Interest Review and Resolution: In order to conform with the HHS final rule, the Certification for Authorized Institutional Representative or Individual Applicant (in the Section WHAT WOULD BE REQUIRED IN PROPOSALS) will be changed to require the institutional representative to certify that any identified conflicts of interests will be managed, reduced or eliminated "prior to the institution's expenditure of any funds under the award." The certification previously required resolution of conflicts "prior to funding the award." This technical change will enable institutions to refrain from reviewing and resolving identified conflicts until after the award is funded, thereby eliminating the need to review and resolve conflicts in proposals that do not get funded. Also, the last sentence of the certification has been separated into two sentences to clarify that conflicts of interest that cannot be satisfactorily managed, reduced or eliminated must be reported to NSF. Accordingly, the certification will now read as follows:

In addition, if the applicant institution employs more than fifty persons, the authorized official of the applicant institution is certifying that the institution has implemented a written and enforced conflict of interest policy that is consistent with the provisions of Grant Policy Manual Section 510; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under the award, in accordance with the institution's conflict of interest policy. Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF.

Deletion of Additional Certification for Principal Investigators and Co-Principal Investigators: In order to conform with the HHS final rule, NSF's policy will be revised to delete the additional Certification for Principal Investigators and Co-Principal Investigators that was previously to be included in Section C-1 of Part II of the Grant Proposal Guide and on Page 2 of the NSF Form 1207, Cover Sheet for Proposal to NSF. Although submission of the additional certification to NSF is no longer required, NSF believes that most institutions' policies will have principal and co-principal investigators certify to the institution that the investigator has read and understands the institution's policy, that all required disclosures were made and that the investigator will comply with any conditions or restrictions imposed by the institution to manage, reduce or eliminate conflicts of interest.
Other Clarifications

1. Application of Policy to Increments of Major Awards. In addition to new NSF proposals, the Policy will apply to certain large ongoing projects such as centers and other activities that are currently being funded by NSF on an incremental basis through cooperative agreements or other agreements for which new proposals may not be submitted for several years. NSF will require that institutions and investigators involved in such projects, at the time of their first funding increment which occurs after October 1, 1995, provide the certifications required by the Policy for all cooperative agreements and for all continuing grant increments exceeding $1,000,000. Such awardees will be advised in advance by the Grants Officer that they will be required to have a policy in place and submit the required certifications as a condition of future funding increments.

2. In addition to the technical changes and clarifications announced above, NSF has made a small number of word changes to resolve minor inconsistencies between its policy and the final HHS rule. These changes are not intended to alter the meaning of any provision of NSF's final policy. The changes are as follows:
   a. In subparagraph b.1 of GPM 510, the word "applicant" will be added before the word "institution." The exclusion from the definition of "significant financial interest" will now read "salary, royalties or other remuneration from the applicant institution."
   b. In subparagraph c of GPM 510, the word "pendency" will be replaced with the word "period." An institutional policy must require financial disclosures to be updated during the period the award is in effect.
   c. In subparagraph d of GPM 510, immediately before the list of examples of conditions or restrictions to manage, reduce or limit conflicts of interest, the words "but are not limited to " will be added after "include."
   d. In the second sentence of subparagraph d of GPM 510, the phrase "research or educational activities funded or proposed for funding by NSF" will be replaced with the phrase "NSF-funded research or educational activities."
   e. Subparagraph g of GPM 510 will be revised to require institutions to maintain records "for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer."
   f. The words "actual or potential" will be deleted in all places where they are used to modify "conflict of interest."

3. Paperwork and Recordkeeping Burden. In cooperation with HHS, NSF has revised its estimate of the paperwork burden associated with the Policy in order to make its estimate consistent with HHS' and to conform to certain changes in the law since NSF issued the final Policy. NSF and HHS have used the same methodology in estimating respective paperwork burdens for their rules.

NSF's revised estimates are as follows:

**REPORTING AND RECORDKEEPING**

<table>
<thead>
<tr>
<th>Number of respondents</th>
<th>Hours per response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Files</strong>*</td>
<td>2,300</td>
<td>4</td>
</tr>
<tr>
<td>Reports of conflict to NSF**</td>
<td>50</td>
<td>80</td>
</tr>
<tr>
<td>Subsequent reports of conflict of interest</td>
<td>7</td>
<td>2</td>
</tr>
</tbody>
</table>

*Consistent with HHS methodology, NSF is now using the number of files expected to be necessary as a basis for estimating the Policy’s recordkeeping burden. NSF estimates that the Policy will apply to approximately 10,000 awards annually and that 23% of all investigators will have disclosures which will require the creation of a file. NSF estimates that 77% of investigators will not have disclosures requiring the creation of a file. NSF estimates that it will require four hours for the establishment and maintenance of a file.

**NSF has estimated that it will receive 200 reports of conflicts of interest. NSF believes that it will receive significantly fewer reports of conflicts because NSF makes fewer awards annually than HHS and because, on average, activities funded by NSF are less likely to affect the financial interests of investigators.

**DISCLOSURE BY INVESTIGATORS**

<table>
<thead>
<tr>
<th>Number of respondents</th>
<th>Hours per response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>38,000</td>
<td>1.0</td>
<td>38,000</td>
</tr>
</tbody>
</table>

**INSTITUTIONAL DISCLOSURE OF POLICY TO INVESTIGATORS***

<table>
<thead>
<tr>
<th>Number of Institutions</th>
<th>Hours per response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,000</td>
<td>20</td>
<td>40,000</td>
</tr>
</tbody>
</table>

***NSF did not initially include an estimate for this aspect of the paperwork burden. However, in light of revisions to the Paperwork Reduction Act, effective October 1, 1995, which will require this element to be estimated, NSF is including such an estimate. NSF’s estimate is consistent with that of HHS.

Total hours for reporting, recordkeeping and disclosure: 91,214.

In accordance with the requirements of the Paperwork Reduction Act of 1980, the National Science Foundation has submitted the information collection requirements cited above to OMB for review and approval. Organizations and individuals desiring to submit comments on the information collection requirements and the estimated burden should direct such comments to the information address cited above and to: NSF Desk Officer, Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

Accordingly, NSF's Investigator Financial Disclosure Policy now reads as follows:
The Investigator Financial Disclosure Policy

NSF’s Investigator Financial Disclosure Policy has the following primary features:

A. A requirement that any NSF grantee employing more than fifty persons maintain "an appropriate written and enforced policy on conflict of interest." 

B. Minimum requirements for what must be in an institution’s policy. These include (a) limited and targeted financial disclosure, (b) designation of a person(s) to review the disclosures and resolve actual or potential problems revealed, (c) enforcement mechanisms, and (d) arrangements for informing NSF of conflicts issues that are not resolved to the satisfaction of the institution.

Changes made to NSF issuances to establish and communicate the Policy are described below. Copies of the NSF Grant General Conditions and the NSF Grant Proposal Guide referenced in the Policy may be obtained from the National Science Foundation, Forms and Publications Unit, 4201 Wilson Blvd., Rm. P-15, Arlington, Virginia 22230, (703) 306-1130, Internet: pubs@nsf.gov. Copies of the NSF Grant Policy Manual may be obtained from the Government Printing Office.

What Would Be Required in Institutional Policies

Grant General Conditions

Insert a new subparagraph b. to Article 23:

Records of investigator financial disclosures and of actions taken to manage conflicts of interest (see Grant Policy Manual Section 510) shall be retained until 3 years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

Renumber subsequent subparagraphs accordingly.

Insert a new Article 33:

For proposals submitted on or after October 1, 1995, if the grantee employs more than fifty persons, the grantee shall maintain an appropriate written and enforced policy on conflict of interest consistent with the provisions of Grant Policy Manual Section 510.

Renumber subsequent articles accordingly.

Grant Policy Manual

Add a new GPM 510 "Conflict of Interest Policies":

a. NSF requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest. Guidance for such policies has been issued by university associations and scientific societies.1

b. An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all significant financial interests of the investigator (including those of the investigator’s spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

The term investigator means the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

The term 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 Small Business Innovation Research Program or Small Business Technology Transfer 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 significant financial interest are
6. Severance of relationships that create conflicts.

If the reviewer(s) reasonably determine that a significant financial interest could affect the design, conduct, or reporting of NSF-funded research or educational activities, then the institution should adopt a policy for managing such conflicts of interest.

The institutional policy must designate one or more persons to review disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest.

Conflicts of interest exist when the reviewer(s) reasonably determine that a significant financial interest could affect the design, conduct, or reporting of NSF-funded research or educational activities.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate 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 the portion of the NSF-funded research that would be affected by the significant financial interests;
5. Divestiture of significant financial interests;
6. Severance of relationships that create conflicts.

If the reviewer(s) reasonably determine that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

e. The institutional policy must include adequate enforcement mechanisms, and provide for sanctions where appropriate.

f. The institutional policy must include arrangements for keeping NSF’s Office of General Counsel appropriately
informed if the institution finds that it is unable to satisfactorily manage a conflict of interest.

g. Institutions must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

What Would Be Required in Proposals

Grant Proposal Guide

Section II.C.1, INSTRUCTIONS FOR PROPOSAL PREPARATION, at the end of the Certification for Authorized Institutional Representative or Individual Applicant, will be revised to add:

A new certification will be added that requires an institutional representative to certify that the institution has implemented a written and enforced policy on conflicts of interest consistent with the provisions of Grant Policy Manual Section 510; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interests will have been satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under the award, in accordance with the institution's conflict of interest policy. Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF.

Page 2 of the NSF Form 1207, Cover Sheet for Proposal to the NSF, will be revised to add the following to the end of the section on Certification for Authorized Institutional Representative or Individual Applicant:

In addition, if the applicant institution employs more than fifty persons, the authorized official of the applicant institution is certifying that the institution has implemented a written and enforced conflict of interest policy that is consistent with the provisions of Grant Policy Manual Section 510; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under the award, in accordance with the institution's conflict of interest policy. Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF.


Lawrence Rudolph,
General Counsel.
“Rules and Regs” Item H.

National Science Foundation rules

When an investigator prepares an NSF grant application, the “authorized organizational representative” (AOR) for the applicant must provide information assuring compliance with conflict of interest rules found in the NSF’s Grant Proposal Guide (GPG).

These CoI rules also appear in the NSF’s Award and Administration Guide (AAG) at http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp#IVA:

[Award and Administration Guide (AAG), Chapter IV.A]

Conflict of Interest Policies

1. NSF requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest and that all conflicts of interest for each award be managed, reduced or eliminated prior to the expenditure of the award funds. If the institution carries out agency-funded research through subawardees, contractors, or collaborators, the institution must take reasonable steps to ensure that:
   
a. the entity has its own policies in place that meet the requirements of this policy; or

b. investigators working for such entities follow the policies of the primary institution.

Guidance for development of such policies has been issued by university associations and scientific societies.

2. An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all significant financial interests of the investigator (including those of the investigator’s spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

The term “investigator” means the principal investigator, co-principal investigators/co-project directors, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.
The term “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 interest (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:

a. salary, royalties or other remuneration from the applicant institution;

b. any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;

c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;

d. income from service on advisory committees or review panels for public or nonprofit entities;

e. 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 5% ownership interest in any single entity; or

f. salary, royalties or other payments that, when aggregated for the investigator and the investigator’s spouse and dependent children, are not expected to exceed $10,000 during the twelve-month period.

3. An institutional policy must ensure that investigators have provided all required financial disclosures at the time the proposal is submitted to NSF. It must also require that those financial disclosures are updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

4. An institutional policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if
any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:

a. public disclosure of significant financial interests;

[b.] monitoring of research by independent reviewers;

c. modification of the research plan;

d. disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;

e. divestiture of significant financial interests; or

f. severance of relationships that create conflicts.

If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

5. The institutional policy must include adequate enforcement mechanisms, and provide for sanctions where appropriate.

6. The institutional policy must include arrangements for keeping NSF’s Office of the General Counsel appropriately informed if the institution finds that it is unable to satisfactorily manage a conflict of interest.10

7. Institutions must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.
[Note] 8. For consistency with the DHHS conflict of interest policy, in lieu of “organization”, NSF is using the term “institution” which includes all categories of proposers.


[Note] 10. Grantee notifications of conflict of interest that cannot be managed, reduced, or eliminated must be submitted electronically via the NSF FastLane system.
“Rules and Regs” Item I.

National Science Foundation rules

Additional statements of NSF rules on conflicts of interest appears in the Award and Administration Guide (AAG) at http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/gpg_2.jsp#bfn12):

Award and Administration Guide (AAG), Chapter II.C.1.e:

Certification Regarding Conflict of Interest: The AOR is required to complete certifications stating that the institution\(^\text{13}\) has implemented and is enforcing a written policy on conflicts of interest, consistent with the provisions of AAG Chapter IV.A.; that, to the best of his/her knowledge, all financial disclosures required by the conflict of interest policy were made; and that conflicts of interest, if any, were, or prior to the institution's expenditure of any funds under the award, will be, satisfactorily managed, reduced or eliminated in accordance with the institution's conflict of interest policy. Conflicts that cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF via use of the Notifications and Requests Module in the NSF FastLane System.

[Note] 13. For consistency with the Department of Health and Human Services conflict of interest policy, in lieu of "organization," NSF is using the term "institution" which includes all categories of proposers.
“Rules and Regs” Item J.

National Science Foundation rules

A policy on investigators’ conflicts of interest also appears in the Grant Policy Manual:

National Science Foundation
Grant Policy Manual
Chapter V. Grantee Standards
510. Conflict of Interest Policies
This can be accessed at
510 CONFLICT OF INTEREST POLICIES

a. NSF requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest. Guidance for such policies has been issued by university associations and scientific societies.

b. An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all significant financial interests of the investigator (including those of the investigator’s spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

The term “investigator” means the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

The term “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 interest (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 Small Business Innovation Research Program or Small Business Technology Transfer Program;
3. income from seminars, lectures, or teaching engagements sponsored by public or non-profit 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 5% 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, are not expected to exceed $10,000 during the twelve month period.

d. An institutional policy must ensure that investigators have provided all required financial disclosures at the time the proposal is submitted to NSF. It must also require that those financial disclosures are updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

e. An institutional policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate 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 the portion of the NSF-funded research that would be affected by significant financial interests;
5. divestiture of significant financial interests; or
6. severance of relationships that create conflicts.

If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

e. The institutional policy must include adequate enforcement mechanisms, and provide for sanctions where appropriate.

f. The institutional policy must include arrangements for keeping NSF’s Office of the General Counsel appropriately informed if the institution finds that it is unable to satisfactorily manage a conflict of interest.11

g. Institutions must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.
[Note] 9. For consistency with the DHHS conflict of interest policy, in lieu of “organization”, NSF is using the term “institution” which includes all categories of proposers.


[Note] 11. Grantee notifications of conflict of interest that cannot be managed, reduced, or eliminated must be submitted electronically via the NSF FastLane system.
“Rules and Regs” Item K.

National Institutes of Health (NIH) Guidelines

General Note

The NIH materials on conflict of interest are easily found through links at http://grants.nih.gov/grants/policy/coi. (Documents from other entities are gathered here because they can be rather difficult to locate.)


NOT-OD-11-109: Issuance of the Final Rule - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors

Notice Number: NOT-OD-11-109

Update: The following update relating to this announcement has been issued:


Key Dates
Release Date: August 22, 2011

Issued by
National Institutes of Health (NIH), Office of Extramural Research

Purpose

The U.S. Department of Health and Human Services (HHS) is issuing a final rule in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf) that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). The final rule specifies compliance dates in the "Dates" section, as discussed further below.

Background

Since the promulgation of these regulations in 1995, the growing complexity of biomedical and behavioral research; the increased interaction among Government, research Institutions, and the private sector in attaining common public health goals while meeting public expectations for research integrity; as well as increased public scrutiny, all have raised questions as to whether a more rigorous approach to Investigator disclosure, institutional management of financial conflicts, and federal oversight is required. The HHS decided to explore the need for revisions to the 1995 regulations by publishing an Advance Notice of Proposed Rulemaking on May 8, 2009 (74 FR 21610).

After analyzing public comments, HHS published a Notice of Proposed Rulemaking (75 FR 28688, hereafter referred to as "NPRM") on May 21, 2010, proposing changes to the 1995 regulations to strengthen accountability and transparency. The proposed changes focused on Investigators' disclosure requirements of significant financial interests (SFIs), Institutions' reporting and management of identified financial conflicts of interest (FCOI), and public disclosure of information regarding Investigator FCOI.

On July 21, 2010, HHS published a Notice (75 FR 42362) extending the 60 day comment period for the NPRM by another 30 days and seeking comment on whether HHS should clarify its authority to enforce compliance with the regulations by Institutions and Investigators, and whether HHS should clarify how the regulations apply in circumstances in which an Investigator or a PHS-funded research project transfers from one Institution to another.

After considering all public comments, and consistent with the proposals articulated in the NPRM, HHS developed the final rule, which includes the following major changes to the 1995 regulations:

<table>
<thead>
<tr>
<th>Topic</th>
<th>1995 Regulations</th>
<th>2011 Final Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Financial Interests (SFI) threshold</td>
<td>De minimis threshold of $10,000 for disclosure generally applies to</td>
<td>De minimis threshold of $5,000 for disclosure generally applies to payments</td>
</tr>
<tr>
<td>Which SFIs need to be disclosed (once the threshold is met)</td>
<td>Only those SFI the Investigator deems related to the PHS-funded research.</td>
<td>All SFI related to the Investigator’s institutional responsibilities.</td>
</tr>
<tr>
<td>Excluded from disclosure requirement</td>
<td>Income from seminars, lectures, or teaching, and service on advisory committees or review panels for public or nonprofit entities</td>
<td>Income from seminars, lectures, or teaching engagements sponsored by and service on advisory 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.</td>
</tr>
<tr>
<td>Types of SFI excluded</td>
<td>All forms of remuneration are included – specific questions such as mutual funds and blind trusts are addressed in FAQ on the NIH website.</td>
<td>Excludes 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.</td>
</tr>
<tr>
<td>Travel reimbursements and sponsored travel</td>
<td>Travel reimbursement is not mentioned explicitly in the regulations but is not excluded from the SFI definition.</td>
<td>Disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). NOT required to disclose 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 will determine if any travel requires further investigation, including determination or disclosure of the monetary value.</td>
</tr>
<tr>
<td>Information on an identified Financial Conflict of Interest (FCOI) reported by the Institution to the PHS Awarding Component</td>
<td>Grant/Contract number; Project Director/Principal Investigator (PD/PI) or Contact PD/PI; Name of Investigator with FCOI; Whether FCOI was managed, reduced, or eliminated</td>
<td>INITIAL REPORT Requirements in 1995 regulations, plus: Name of the entity with which the Investigator has a FCOI; Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria; Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amts between $20K-$100K by increments of $20K; amts above $100K by increments of $50K or statement that a value cannot be readily determined; A description how the financial interest relates to PHS-funded research and the</td>
</tr>
<tr>
<td>Subrecipient Institutions/Investigators and Reporting of identified FCOIs</td>
<td>Institutions must take reasonable steps to ensure that Investigators working for subs comply with the regulations 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 the regulations.</td>
<td>Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations.</td>
</tr>
<tr>
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</tr>
<tr>
<td>Public Accessibility</td>
<td>No requirement</td>
<td>Make information available concerning identified FCOIs held by senior/key personnel via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the rule. This information will include at a minimum the Investigator’s name; the Investigator’s title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, 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.</td>
</tr>
<tr>
<td>FCOI training</td>
<td>No requirement</td>
<td>Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances: institutional FCOI policies change in a manner that affects Investigator requirements an Investigator is new to an Institution an Institution finds an Investigator noncompliant with Institution’s FCOI policy or management plan.</td>
</tr>
</tbody>
</table>
Retrospective Review
("Mitigation plan," discussed in NPRM)

Not mentioned

Institution is required to conduct a retrospective review in those cases of non-compliance with the regulations. The Institution will be required to notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.

Compliance Dates:

An Institution applying for or receiving PHS funding from a grant, cooperative agreement, or contract that is covered by the final rule must be in full compliance with all of the revised regulatory requirements:

- No later than 365 calendar days after the date of publication in the Federal Register, i.e. August 24, 2011; and
- Immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described in the final rule.

In the interim, Institutions should continue to comply with the 1995 regulations and report Investigator FCOIs to the Public Health Service (PHS) Awarding Component as required in the 1995 regulations.

NIH grant and cooperative agreement award recipients should continue to submit FCOI reports using the electronic Research Administration (eRA) Commons FCOI Module. Once the institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met. Therefore, if the eRA Commons FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment that addresses the minimum elements of the FCOI report as provided in 42 CFR 50.605(b)(3).

Inquiries

Please direct all inquiries to:

Office of Policy for Extramural Research Administration
Division of Grants Compliance and Oversight
6701 Rockledge Drive MSC 7974
Bethesda, MD 20892-7974
Voice: (301) 435-0938
Fax: (301) 435-3059

or

FCOICompliance@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
“Rules and Regs” Item L.

The Bayh-Dole Act (1980)—“Policy and objective”

Investigators receiving federal funding have developed many inventions with commercial potential. The Bayh-Dole Act, passed in 1980, sought to promote the commercialization of these inventions by allowing and encouraging institutions to patent and develop their innovations. With the change came an increased risk of conflict between the role of investigator/teacher and the role of entrepreneur. Similarly, universities have had to navigate their duties to multiple stakeholders.


It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.
“Rules and Regs” Item M.

**Food and Drug Administration (FDA).**
Citation: 21 CFR § 19.
Code of Federal Regulations
Title 21. Food and Drugs
Chapter 1. Food and Drug Administration, Department of Health and Human Services (Continued)
Subchapter A. General

**Part 19. Standards of Conduct and Conflicts of Interest**
[4 pages, with printed numbers 188-191]
(Copy provided is current as of April 1, 2011: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol1/pdf/CFR-2011-title21-vol1-part19.pdf. To check for more recent versions, go to http://www.gpoaccess.gov/cfr/. Select the most recent year. If Title 21 does not yet appear for that year, check the previous year.)
However, no such additional briefs will be considered unless so requested.

(i) If any party demonstrates to the satisfaction of the entity deciding the appeal (currently the DAB) that additional evidence not presented at the hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the entity deciding the appeal may remand the matter to the presiding officer for consideration of the additional evidence.

(j) The Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) will issue a decision on the appeal within 60 days, if practicable, of the due date for submission of the appellee's brief. In the decision, the entity deciding the appeal may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by the presiding officer in the initial decision. If the entity deciding the appeal declines to review the case, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after the declination by the entity deciding the appeal.

(k) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

[60 FR 38636, July 27, 1995, as amended at 71 FR 5979, Feb. 6, 2006]

§ 17.48 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the presiding officer or by any of the parties is grounds for vacating, modifying, or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the presiding officer or the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) to be inconsistent with substantial justice. The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

§ 17.51 Judicial review.

(a) The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved. Although the filing of a petition for judicial review does not stay a decision under this part, a respondent may file a petition for stay of such decision under § 10.35 of this chapter.

(b) The Chief Counsel of FDA has been designated by the Secretary of Health and Human Services as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the entity deciding the appeal (currently the DAB).

(c) Exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review.

§ 17.54 Deposit in the Treasury of the United States.

All amounts assessed pursuant to this part shall be delivered to the Director, Division of Financial Management (HFA-100), Food and Drug Administration, rm. 11-61, 5600 Fishers Lane, Rockville, MD 20857, and shall be deposited as miscellaneous receipts in the Treasury of the United States.

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

Subpart A—General Provisions

Sec.
19.1 Scope.
19.5 Reference to Department regulations.
19.6 Code of ethics for government service.
19.10 Food and Drug Administration Conflict of Interest Review Board.
Food and Drug Administration, HHS

Subpart B—Reporting of Violations

19.21 Duty to report violations.

Subpart C—Disqualification Conditions

19.45 Temporary disqualification of former employees.
19.55 Permanent disqualification of former employees.


SOURCE: 42 FR 15615. Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 19.1 Scope.
This part governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 19.5 Reference to Department regulations.
(a) The provisions of 45 CFR part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in subpart L of 45 CFR part 73.
(b) The provisions of 45 CFR part 73a supplement the Department standards of conduct and apply only to Food and Drug Administration employees except special government employees.

§ 19.6 Code of ethics for government service.
The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:
1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.
2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.
3. Give a full day’s labor for a full day’s pay: giving to the performance of his duties his earnest effort and best thought.

§ 19.10 Food and Drug Administration Conflict of Interest Review Board.
(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and Drug Administration that are forwarded to it by: (1) The Associate Commissioner for Management and Operations or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Management and Operations on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Ethics and Program Integrity, Office of Management and Operations, shall serve as executive secretary of the Review Board.
(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Management and Operations for resolution, except that reporting of apparent violations of law are governed by §19.21.
§ 19.21

(c) All general policy relating to conflicts of interest shall be established in guidance documents pursuant to the provisions of § 10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Freedom of Information Staff, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of § 20.63 of this chapter.


Subpart C—Disqualification Conditions

§ 19.45 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee, shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term official responsibility means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

§ 19.55 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or other particular matter involving a
Food and Drug Administration, HHS

specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise as a Food and Drug Administration employee.

PART 20—PUBLIC INFORMATION

Subpart A—Official Testimony and Information

Sec.
20.1 Testimony by Food and Drug Administration employees.
20.2 Production of records by Food and Drug Administration employees.
20.3 Certification and authentication of Food and Drug Administration records.

Subpart B—General Policy

20.20 Policy on disclosure of Food and Drug Administration records.
20.21 Uniform access to records.
20.22 Partial disclosure of records.
20.23 Request for existing records.
20.24 Preparation of new records.
20.25 Retroactive application of regulations.
20.26 Indexes of certain records.
20.27 Submission of records marked as confidential.
20.28 Food and Drug Administration determinations of confidentiality.
20.29 Prohibition on withdrawal of records from Food and Drug Administration files.
20.30 Food and Drug Administration Freedom of Information Staff.
20.31 Retention schedule of requests for Food and Drug Administration records.
20.32 Disclosure of Food and Drug Administration employee names.
20.33 Form or format of response.
20.34 Search for records.

Subpart C—Procedures and Fees

20.40 Filing a request for records.
20.41 Time limitations.
20.42 Aggregation of certain requests.
20.43 Multitrack processing.
20.44 Expedited processing.
20.45 Fees to be charged.
20.46 Waiver or reduction of fees.
20.47 Situations in which confidentiality is uncertain.
20.48 Judicial review of proposed disclosure.
20.49 Denial of a request for records.
20.50 Nonspecific and overly burdensome requests.
20.51 Referral to primary source of records.

Subpart D—Exemptions

20.60 Applicability of exemptions.
20.61 Trade secrets and commercial or financial information which is privileged or confidential.
20.62 Inter- or intra-agency memoranda or letters.
20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.
20.64 Records or information compiled for law enforcement purposes.
20.65 National defense and foreign policy.
20.66 Internal personnel rules and practices.

Subpart E—Limitations on Exemptions

20.80 Applicability of limitations on exemptions.
20.81 Data and information previously disclosed to the public.
20.82 Discretionary disclosure by the Commissioner.
20.83 Disclosure required by court order.
20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.
20.85 Disclosure to other Federal government departments and agencies.
20.86 Disclosure in administrative or court proceedings.
20.87 Disclosure to Congress.
20.88 Communications with State and local government officials.
20.89 Communications with foreign government officials.
20.90 Disclosure to contractors.
20.91 Use of data or information for administrative or court enforcement action.

Subpart F—Availability of Specific Categories of Records

20.100 Applicability; cross-reference to other regulations.
20.101 Administrative enforcement records.
20.102 Court enforcement records.
20.103 Correspondence.
20.104 Summaries of oral discussions.
20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.
20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.
“Rules and Regs” Item N.

Food and Drug Administration (FDA).

Citation: 21 CFR § 54.
Code of Federal Regulations
Title 21. Food and Drugs
Chapter 1. Food and Drug Administration, Department of Health and Human Services (Continued)
Subchapter A. General
Part 54. Financial Disclosure by Clinical Investigators
[4 pages, with printed numbers 295-298]

(Copy provided is current as of April 1, 2011:
http://www.gpoaccess.gov/cfr/. Select the most recent year. If Title 21 does not yet appear for that year, check the previous year.)
PART 54—FINANCIAL DISCLOSURE
BY CLINICAL INVESTIGATORS

§54.1 Purpose.
(a) The Food and Drug Administration (FDA) evaluates clinical studies submitted in marketing applications, required by law, for new human drugs and biological products and marketing applications and reclassification petitions for medical devices.

(b) The agency reviews data generated in these clinical studies to determine whether the applications are approvable under the statutory requirements. FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias. One potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the sponsor of the covered study. This section and conforming regulations require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies. FDA will use this information, in conjunction with information about the design and purpose of the study, as well as information obtained through on-site inspections, in the agency’s assessment of the reliability of the data.

§54.2 Definitions.
For the purposes of this part:
(a) Compensation affected by the outcome of clinical studies means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

(b) Significant equity interest in the sponsor of a covered study means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds $50,000 during the time the clinical investigator is carrying out the study and for 1 year following completion of the study.

(c) Proprietary interest in the tested product means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

(d) Clinical investigator means only a listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

(e) Covered clinical study means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple
§ 54.3 Scope.

The requirements in this part apply to any applicant who submits a marketing application to FDA for approval of a drug, device, or biologic product. The applicant is responsible for submitting the appropriate certification and disclosure statement required in this part.

§ 54.4 Certification and disclosure requirements.

For purposes of this part, an applicant must submit a list of all clinical investigators who conducted covered clinical studies to determine whether the applicant's product meets FDA's marketing requirements, identifying those clinical investigators who are full-time or part-time employees of the sponsor of each covered study. The applicant must also completely and accurately disclose or certify information concerning the financial interests of a clinical investigator who is not a full-time or part-time employee of the sponsor for each covered clinical study. Clinical investigators subject to investigational new drug or investigational device exemption regulations must provide the sponsor of the study with sufficient accurate information needed to allow subsequent disclosure or certification. The applicant is required to submit for each clinical investigator who participates in a covered study, either a certification that none of the financial arrangements described in §54.2 exist, or disclose the nature of those arrangements to the agency. Where the applicant acts with due diligence to obtain the information required in this section but is unable to do so, the applicant shall certify that despite the applicant's due diligence in attempting to obtain the information, the applicant was unable to obtain the information and shall include the reason.

(a) The applicant (of an application submitted under sections 505, 506, 510(k), 513, or 515 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act) that relies in whole or in part on clinical studies shall submit, for each clinical investigator who participated in a covered clinical study, either a certification described in paragraph (a)(1) of this section or a disclosure statement described in paragraph (a)(3) of this section.

(1) Certification: The applicant covered by this section shall submit for all clinical investigators (as defined in §54.2(d)), to whom the certification applies, a completed Form FDA 3454 attesting to the absence of financial interests and arrangements described in paragraph (a)(3) of this section. The form shall be dated and signed by the chief financial officer or other responsible corporate official or representative.

(2) If the certification covers less than all covered clinical data in the application, the applicant shall include in the certification a list of the studies covered by this certification.
(3) Disclosure Statement: For any clinical investigator defined in §54.2(d) for whom the applicant does not submit the certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:

(i) Any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of a covered clinical trial, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

(ii) Any significant payments of other sorts from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

(iii) Any proprietary interest in the tested product held by any clinical investigator involved in a study;

(iv) Any significant equity interest in the sponsor of the covered study held by any clinical investigator involved in any clinical study; and

(v) Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

(b) The clinical investigator shall provide to the sponsor of the covered study sufficient accurate financial information to allow the sponsor to submit complete and accurate certification or disclosure statements as required in paragraph (a) of this section. The investigator shall promptly update this information if any relevant changes occur in the course of the investigation or for 1 year following completion of the study.

(c) Refusal to file application. FDA may refuse to file any marketing application described in paragraph (a) of this section that does not contain the information required by this section or a certification by the applicant that the applicant has acted with due diligence to obtain the information but was unable to do so and stating the reason.


§54.5 Agency evaluation of financial interests.

(a) Evaluation of disclosure statement. FDA will evaluate the information disclosed under §54.4(a)(2) about each covered clinical study in an application to determine the impact of any disclosed financial interests on the reliability of the study. FDA may consider both the size and nature of a disclosed financial interest (including the potential increase in the value of the interest if the product is approved) and steps that have been taken to minimize the potential for bias.

(b) Effect of study design. In assessing the potential of an investigator's financial interests to bias a study, FDA will take into account the design and purpose of the study. Study designs that utilize such approaches as multiple investigators (most of whom do not have a disclosable interest), blinding, objective endpoints, or measurement of endpoints by someone other than the investigator may adequately protect against any bias created by a disclosable financial interest.

(c) Agency actions to ensure reliability of data. If FDA determines that the financial interests of any clinical investigator raise a serious question about the integrity of the data, FDA will take any action it deems necessary to ensure the reliability of the data including:

(1) Initiating agency audits of the data derived from the clinical investigator in question;

(2) Requesting that the applicant submit further analyses of data, e.g., to evaluate the effect of the clinical investigator's data on overall study outcome;

(3) Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; and

(4) Refusing to treat the covered clinical study as providing data that can be the basis for an agency action.

§54.6 Recordkeeping and record retention.

(a) Financial records of clinical investigators to be retained. An applicant who has submitted a marketing application containing covered clinical studies shall keep on file certain information
pertaining to the financial interests of clinical investigators who conducted studies on which the application relies and who are not full or part-time employees of the applicant, as follows:

(1) Complete records showing any financial interest or arrangement as described in §54.4(a)(3)(i) paid to such clinical investigators by the sponsor of the covered study.

(2) Complete records showing significant payments of other sorts, as described in §54.4(a)(3)(ii), made by the sponsor of the covered study to the clinical investigator.

(3) Complete records showing any financial interests held by clinical investigators as set forth in §54.4(a)(3)(iii) and (a)(3)(iv).

(b) Requirements for maintenance of clinical investigators' financial records.

(1) For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for 2 years after the date of approval of the application.

(2) The person maintaining these records shall, upon request from any properly authorized officer or employee of PDA, at reasonable times, permit such officer or employee to have access to and copy and verify these records.

PART 56—INSTITUTIONAL REVIEW BOARDS

Subpart A—General Provisions

§56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(46 FR 8975, Jan. 27, 1981, unless otherwise noted.)

§56.102 Definitions.

As used in this part:

(a) Act means the Federal Food, Drug, and Cosmetic Act, as amended