

## FAQ'S

### A. General Questions

1. **What is the purpose of this regulation? (Institution and Investigator)**

The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation. (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>).

2. **When are Institutions required to comply with the 2011 revised regulation? (Institution)**

An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a).

3. **Is the 2011 revised regulation retroactive? (Institution)**

No. The revised regulation will apply to each grant or cooperative agreement with an issue date of the Notice of Award that is subsequent to the compliance dates of the final rule (including noncompeting continuations) no later than August 24, 2012 and immediately upon making its Financial Conflict of Interest policy publicly accessible. Through their policies, however, Institutions may choose to apply the revised regulations to all active PHS awards. For example, Institutions may choose, in their Financial Conflict of Interest policy, to implement the regulation on a single date for all PHS-funded awards rather than implementing the regulation sequentially on the specific award date of each individual project.

4. **What is the most significant difference between the 1995 regulation and the 2011 revised regulation? (Institution and Investigator)**

The 2011 revised regulation includes comprehensive changes, focusing on these areas in particular:

- Definition of Significant Financial Interest
- Extent of Investigators' disclosure of information to Institutions regarding their Significant Financial Interests;
- Institutions' management of identified Financial Conflicts of Interest
- Information reported to the PHS funding component (e.g., NIH);
- Information made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel); and
- Investigator training.

5. **Where can I find additional information? (Institution and Investigator)**

More information specific to grants and cooperative agreements is available on the Financial Conflict of Interest Web Page of the Grants Policy and Guidance section of the NIH Office of Extramural Research home page (<http://grants.nih.gov/grants/policy/coi/index.htm>.)

6. **I have heard there is a special requirement for clinical research. Is this true? (Institution and Investigator)**

Yes. In any case in which the HHS determines that an NIH-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 conflicting interest that was not managed or reported by the Institution as required by the regulation, the Institution must require the Investigator(s) 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. Institution's Financial Conflict of Interest policy may have additional requirements.

### B. Administration

7. **What actions should be taken in the event that an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or management plan? (Institution)**

When an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or the management plan, the Institution shall within 120 days:

- a. a) complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
- b. b) document the retrospective review consistent with the regulation; and
- c. c) document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, the Institution shall notify the NIH promptly and submit a mitigation report to the NIH that shall address the following:

- 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.

Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation. 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 NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

In addition, if the NIH determines that one of its funded clinical research projects 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, 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.

**What are the penalties/fines for failure to comply with the 2011 revised regulation? (Institution)**

The FCOI regulation (42 CFR Part 50 Subpart F) does not include a "fine structure" for noncompliance. However, Section 50.604 (j) requires Institutions to establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate. In addition, Section 50.506 permits NIH to take appropriate action or direct the Institution to take action to maintain appropriate objectivity in Public Health Service-funded research.

In addition, the NIH Grants Policy Statement (GPS) (10-1-2011)

([http://grants.nih.gov/grants/policy/nihgps\\_2011/index.htm](http://grants.nih.gov/grants/policy/nihgps_2011/index.htm)), which serves as a term and condition of all NIH awards, provides information in chapter 8.5 Special Award Conditions and Enforcement Actions on actions NIH may take in those situations when a grantee fails to comply with the terms and conditions of award

([http://grants.nih.gov/grants/policy/nihgps\\_2011/nihgps\\_ch8.htm#\\_Toc271264977](http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm#_Toc271264977)).

Depending on the severity and duration of the noncompliance, NIH may take one or more actions. For example, NIH may impose special conditions on a grant to allow the grantee to take corrective action. In addition, if a grantee has failed to materially comply with the terms and conditions of award, NIH may take action to wholly or partly suspend the grant, pending corrective action, or may terminate the grant. The regulatory procedures that pertains to suspension and termination are specified in 45 CFR parts 74.61 and 74.62, and in part 92.43.

**If an Institution identifies an FCOI prior to the NIH's issuance of a Notice of Award, may the Institution incur preaward costs prior to submitting the FCOI report to the NIH? (Institution)**

Yes. As provided by NIH grants policy, Institutions may, at their own risk, incur preaward costs. However, the Institution must submit the FCOI report to the NIH through the eRA Commons FCOI Module prior to the Institution's expenditure of NIH funds authorized under the award, that is, after the Notice of Award is issued and before the specific amount is charged to an NIH award.

## **C. Applicability**

### **Who is covered by the regulation? (Institution and Investigator)**

The regulation is applicable to each Institution that is applying for, or that receives, NIH research funding by means of a grant or cooperative agreement and, through the implementation of the regulation by the Institution, to each Investigator who is planning to participate in, or is participating in, such research. The regulation, however, does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications. For purposes of financial disclosure only, the regulation covers the Investigator's spouse and dependent children. The regulation also applies to those few cases where an individual, rather than an Institution, is applying for or receives NIH research funding. However, in those cases, the NIH will make case-by-case determinations on the steps an Institution or an Investigator must take, consistent with the regulation, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a Financial Conflict of Interest of the individual.

### **Does this regulation apply to all grants and cooperative agreements awarded by the NIH? (Institution and Investigator)**

No. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) Small Business Technology Transfer (STTR) applications. The regulation applies to research and includes any activity for which research funding is available from the NIH through a grant or cooperative agreement. The regulation explicitly applies to research authorized under the PHS Act or other statutory authority, such as a research grant, career development grant, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

### **Does the regulation apply to conference grants (R13 and U13 award mechanisms) in support of sponsored and directed international, national, or regional meetings, conferences and workshops? (Institution and Investigator)**

Yes. The regulation defines "Research" as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement. The definition of the term "Research" provides a non-exhaustive list of examples of the different types of NIH-funding mechanisms to which the regulation applies such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award. The only award programs that are excluded from the regulation are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I applications.

### **Does the regulation apply to an S06 (Minority Biomedical Research Support) or other "S" award mechanisms? (Institution and Investigator)**

Yes. The regulation defines "Research" as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement. The definition of the term "Research" provides a non-exhaustive list of examples of the different types of NIH-funding mechanisms to which the regulation applies such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award. The only award programs that are excluded from the regulation are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Phase I applications.

### **Does the regulation apply to subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members)? (Institution)**

Yes. The 2011 revised regulation is applicable to each Institution that applies for or receives NIH funding for research through grants or cooperative agreements and, through the implementation of the regulation by each Institution, to each Investigator planning to participate in, or participating in, such research. A subrecipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the NIH-funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters.

Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest regulation applies to subrecipients (e.g., subcontractors or consortium members). See 42 CFR 50.604 (c).

**I am a collaborator/consultant/subgrantee/subcontractor/subrecipient performing research funded by the NIH but am not employed directly by the Institution that received the award. Does this regulation apply to me? (Investigator)**

Yes. If you meet the definition of an "Investigator," the PHS regulation applies to you. The awardee institution is required to incorporate as part of a written agreement with the subrecipient terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient apply to the subrecipient's Investigators. Please consult the appropriate Institutional official or the written agreement to determine which policy applies.

**I am a post-doctoral fellow receiving funding from the NIH. Does this regulation apply to me? (Investigator)**

Yes. If you meet the definition of an "Investigator," the PHS regulation applies to you. The regulation is applicable to each Institution that applies for or receives NIH grant awards or cooperative agreements for research and, through the implementation of the regulation by each Institution, to each Investigator who is planning to participate in, or is participating in such research. As noted above, an Investigator is defined as 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 NIH, or proposed for such funding. Thus, if a post-doctoral fellow meets the definition of an Investigator, he or she would be subject to the regulation if the NIH funding is for research. You should consult with your Institution's designated official(s) to ensure you comply with the appropriate requirements.

**I am a graduate student working on research funded by the NIH. Am I subject to the requirements of the Financial Conflict of Interest regulation? (Investigator)**

Yes. If you meet the definition of an "Investigator," the PHS regulation applies to you. As stated above, the term "Investigator" is defined to encompass individuals "responsible for the design, conduct or reporting" of research funded by the NIH. Be sure to confirm with your Institutional designated official(s) whether you, as a graduate student, meet this definition.

**I have heard about the financial disclosure requirements imposed by the Ethics in Government Act for Investigators employed at the NIH. Do these regulations apply to me? (Institution and Investigator)**

No. The Financial Conflict of Interest regulation discussed in this FAQ document (42 CFR Part 50 Subpart F) is distinct from the ethics rules that apply to NIH employees.

**Do these new regulations apply to all Federal funding, or only funding from NIH? (Institution)**

As noted in Section 50.602 of the regulation, the Final Rule applies to Institutions that apply for, or that receive Public Health Service (PHS) research funding by means of a grant or cooperative agreement. Section 50.603 defines "PHS", "PHS Awarding Component" and "Research" as follows:

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.

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.

Therefore, this regulation applies to institutions that receive Federal funding for research by a PHS Awarding Component. The NIH is a PHS Awarding Component. Institutions should contact

the applicable PHS Awarding Component to determine whether the 2011 revised regulation applies to a PHS-funded award.

## **D. Definitions**

### **What is the Public Health Service? (Institution and Investigator)**

*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 NIH.

### **For purposes of the Financial Conflict of Interest regulation, what is an "Institution?" (Institution and Investigator)**

*Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives NIH research funding.

### **What is an "Entity" as used in the Financial Conflict of Interest regulation? (Institution and Investigator)**

*Entity* means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

### **As referenced in the 2011 revised regulation, who are the "senior/key personnel" in NIH-funded research? (Institution and Investigator)**

*Senior/Key Personnel* means the Project Director/Principal Investigator (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 NIH by the Institution under the regulation.

### **Who is considered an "Investigator" for the purpose of this regulation? Is it only the Principal Investigator? (Institution and Investigator)**

No. "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 (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases.

In addition, the Investigator's spouse and dependent children have been eliminated from the definition of "Investigator" under the 2011 revised regulation; however, they are referenced in the definition of "Significant Financial Interest" because the Investigator must also disclose Significant Financial Interests of his/her spouse and dependent children. (see definition of Significant Financial Interest).

### **What are "institutional responsibilities?" (Institution and Investigator)**

"Institutional responsibilities" are defined by the 2011 revised regulation as an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict 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. The Institution can include other professional responsibilities within the definition, as appropriate.

### **What is a "Financial Conflict of Interest?" (Institution and Investigator)**

A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

### **What financial interests are covered by the regulation and what is a Significant Financial Interest? (Institution and Investigator)**

The regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable.

The 2011 revised regulation defines a "Significant Financial Interest" as follows:

“(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 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.”

The Institution may have more stringent financial disclosure requirements. Please refer to the Institution’s conflict of interest policy and confer with the Institution’s designated official(s) to determine the Institution’s disclosure requirements.

#### **How is a “new” Significant Financial Interest (SFI) defined? (Investigator and Institution)**

A new SFI is a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a “new” SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

## **E. Disclosure**

**How does the definition of Significant Financial Interest under the 2011 revised regulation differ from the 1995 regulatory definition of Significant Financial Interest? (Institution and Investigator)**

The definition of Significant Financial Interest under the 2011 revised regulation differs from the 1995 definition of Significant Financial Interest in a number of respects.

- *Institutional responsibilities:*  
Under the 2011 FCOI regulation, Significant Financial Interests that are subject to disclosure by an Investigator to an Institution are those that reasonably appear to be related to the Investigator's "Institutional responsibilities," as defined by the Institution. As a result, when read in conjunction with the revised Investigator disclosure requirements under 42 CFR 50.604, the revised Significant Financial Interest definition results in the disclosure by Investigators to Institutions of a wider array of interests on a more frequent basis. In addition to their own, Investigators are required to disclose the Significant Financial Interests of his/her spouse and dependent children.  
Under the 1995 regulation, Investigators were required to disclose their Significant Financial Interests related to their PHS-funded research.
- *Monetary threshold:*  
The 2011 Significant Financial Interest definition lowers the de minimis threshold to \$5,000 and, in some circumstances, eliminates the existing monetary thresholds for disclosure.  
Under the 1995 FCOI regulation, a Significant Financial Interest did not include an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, met both of the following tests: Did not exceed \$10,000 in value and did not represent more than a five percent (5%) ownership interest in any single entity. Similarly, a Significant Financial Interest did not include payments (e.g., salary) that, when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, were not expected to exceed \$10,000.  
The 2011 definition also differentiates between remuneration to the Investigator (and the Investigator's spouse and dependent children) from a publicly traded entity and remuneration from a non-publicly traded entity. With regard to a publicly traded entity, a monetary threshold of \$5,000 applies to the aggregated amount of any remuneration received from the entity in the twelve months preceding disclosure and the value of any equity interest as of the date of disclosure. With regard to a 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).
- *Timing:*  
The revised Significant Financial Interest definition changes the timing for determining whether remuneration represents a Significant Financial Interest.  
The 1995 regulation excluded aggregated payments (including salary and royalties) that were "not expected to exceed" the monetary threshold "over the next twelve months."  
Under the 2011 definition, at issue is any remuneration received from an entity "in the twelve months preceding the disclosure and the value of any publicly traded equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000."
- *Examples of payment for services:*  
The 1995 definition referenced as examples of payments for services receipt of consulting fees or honoraria.  
The 2011 revised regulation adds "paid authorship" as an additional example of payment for services.
- *Royalties & Intellectual Property:*  
Under the 1995 regulation, royalties were subject to the \$10,000 threshold if not received from the applicant institution.  
Under the 2011 revised regulation, the preamble clarifies that a threshold of \$5,000 applies to licensed intellectual property rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights (see page 53265.) However, intellectual property rights assigned to the Institution and agreements to

share in royalties related to such rights are still excluded from the Significant Financial Interest definition.

▪ *Reimbursed or Sponsored Travel:*

Under the 1995 regulation, there was no specific requirement to disclose reimbursed or sponsored travel.

Under the 2011 revised regulation, and with the express exceptions noted therein, Investigators 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 the Investigator's institutional responsibilities as prescribed by the Institution's Financial Conflict of Interest (FCOI) policy (i.e., specify the details of the disclosure which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration). The institutional official 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 PHS-funded research. This disclosure is addressed in the definition of "Significant Financial Interest," (SFI) which makes it subject to the following considerations:

(1) Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research.

(2) Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

(3) Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.

▪ *Exclusions:*

The 2011 revised regulation modifies the types of interests that are specifically excluded from the Significant Financial Interest definition. The exclusions are:

- salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
- any ownership interests 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 in 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;
- income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

Unlike in the 1995 Financial Conflict of Interest regulation, income from non-profit entities other than federal, state, or local government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an Institution of higher education for the types of activities described above would be subject to the Significant Financial Interest definition.

In addition, the SBIR/STTR applicant exclusion under the 1995 regulation was broadened to include any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization (whether or not an SBIR/STTR applicant).

**Who is required to disclose financial interests? (Institution and Investigator)**

Under the 2011 revised regulation, Investigators (as defined by the regulation) who are planning to participate in, or are participating in, NIH-funded research, with the exception of Phase I SBIR/STTR applications, are required to disclose to the designated official(s) of the

Institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

**What information must the Institution obtain from Investigators and when should it be collected? (Institution and Investigator)**

Under the 2011 revised regulation, Investigators are required to disclose their Significant Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

- (1) no later than at the time of application for NIH-funded research;
- (2) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
- (3) at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

**What about financial interests acquired or discovered during the award period subsequent to the submission of the initial report? (Institution and Investigator)**

Investigators have an ongoing obligation to disclose Significant Financial Interests throughout the awarded project period. Under the 2011 revised Financial Conflict of Interest regulation, Investigators must update financial disclosures of Significant Financial Interests to their Institutions within thirty (30) days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. The Institution's designated official(s) will have sixty (60) days to review the Significant Financial Interest disclosure, determine whether the Significant Financial Interest is related to NIH-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, or will be, taken to manage the Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institution must submit an FCOI report to the NIH within this same 60-day period.

**What about payments to or assets held by my spouse or dependent children? Must these financial interests be disclosed? (Investigator)**

Yes. Please see the question on the definition of "Significant Financial Interests." The financial interests that must be disclosed by the Investigator include the aggregated amounts or values of financial interests held by the Investigator and his/her spouse and dependent children.

**How long does an Investigator have to disclose a newly acquired or discovered Significant Financial Interest? (Institution and Investigator)**

Under the 2011 revised regulation, each Investigator who is participating in the NIH-funded research must submit to his/her Institution an updated disclosure of Significant Financial Interests within thirty (30) days of acquiring or discovering a new Significant Financial Interest or a Significant Financial Interest that was not disclosed timely.

**Do I need to disclose salary paid to me by my Institution as an Investigator? (Investigator)**

No. Salary, royalties, or other remuneration from your employing or appointing Institution is not included.

**Do I need to disclose the occurrence of any reimbursed or sponsored travel related to my institutional responsibilities? (Investigator)**

Yes. The regulation requires Investigators to 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 the Investigator's institutional responsibilities. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- 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.

Check with your Institution's FCOI policy since it will specify the details of this disclosure, which will include, at a minimum, the following:

- purpose of the trip,
- the identity of the sponsor/organizer
- the destination, and
- the duration.

In addition, the Institution's FCOI policy may also determine if additional information is needed, such as a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the NIH-funded research.

**Does an Investigator need to disclose all reimbursed or sponsored travel, no matter the dollar level, if it is reimbursed or sponsored by sources other than those excluded from disclosure (i.e., Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education)? (Institution and Investigator)**

Yes. The 2011 revised regulation does not provide a de minimis threshold for the disclosure of reimbursed or sponsored travel. The 2011 revised regulation requires disclosure of basic information about such travel including at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration but not including the dollar amount. As provided in the regulation, 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. The regulation does not specify the process to be used by Institutions for review of Investigator travel disclosures; however, the Institution is responsible for determining whether such travel constitutes a Financial Conflict of Interest with PHS-funded research. Travel to scientific meetings and to present Investigator's research to colleagues and other interested parties is an integral part of the scientific research enterprise and affords many important opportunities for forging relationships and collaborations among researchers. The provisions in the revised regulations are not intended to discourage this type of travel but require the disclosure of the occurrence of any reimbursed or sponsored travel related to the Investigator's institutional responsibilities provided the travel is not sponsored or reimbursed by those identified sources excluded in the final rule.

**To whom should I disclose my financial interests? (Investigator)**

Your Institution will designate an Institutional official(s) to solicit and review financial disclosure statements. Please consult your Institution's conflict of interest policy and procedures and/or your Institution's designated official(s) for more information about the disclosure requirements and procedures at your Institution.

**When should I disclose my financial interests to the Institution? (Investigator)**

Please refer to your Institution's conflict of interest policy. In accordance with the 2011 revised regulation, Significant Financial Interests must be disclosed to the Institutional designated official(s) by the time an application is submitted to the NIH for funding, within thirty (30) days of discovering or acquiring a new Significant Financial Interest, and on an annual basis at intervals thereafter to be determined by your Institution.

**What happens if my financial interests change during the award period? (Investigator)**

The 2011 revised regulation requires each Investigator who is participating in NIH-funded research to submit an updated disclosure of Significant Financial Interest to the Institution's designated official(s) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. Be sure to check with your Institutional policy since the policy may have a more restrictive reporting requirement. The Institution's designated official(s) are required to review the updated financial disclosure of Significant Financial Interest, determine whether the Significant Financial Interest is related to the NIH-funded research and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest and take appropriate action to manage any Financial Conflict of Interests and report such FCOI(s) to NIH.

**I am an Investigator in an NIH-supported clinical trial network. My network has developed a study-wide policy for the trial that requires me to disclose my Significant Financial Interests to my network's steering committee/operations office on an annual**

**basis. Do I need to disclose my Significant Financial Interests to my Institution as well? (Investigator)**

Reporting your Significant Financial Interests to a steering committee or other entity overseeing an NIH-supported clinical trial may not fulfill your responsibilities under your Institution's Financial Conflict of Interest policy. If you are an Investigator as defined by the regulation an NIH-supported grant award, then you must disclose your Significant Financial Interests to your Institution in accordance with its Financial Conflict of Interest policy. Please refer to your Institution's policy (which may integrate network disclosures) and/or consult the appropriate Institutional designated official(s) to verify your Institution's disclosure requirements and how they apply to your research.

**Is income from all non-profit institutions excluded from the definition of Significant Financial Interest? (Institution and Investigator)**

No. The 2011 revised regulation states that 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 is excluded from the definition of Significant Financial Interest. Such income from all other sources is included in the definition of Significant Financial Interest and, accordingly, must be disclosed.

**What must be disclosed by an Investigator who is employed by a University and has equity interest in a for-profit company? (Institution and Investigator)**

If the Investigator is supported by an NIH grant through the University (i.e., the University is the grantee), the Investigator must disclose the equity interest in the for-profit company to the University if the Significant Financial Interest is related to the Investigator's institutional responsibilities.

**Am I required to disclose interests in mutual funds or retirement accounts? (Institution and Investigator)**

Maybe. The 2011 revised regulation does not require the disclosure of 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. Please refer to your Institution's Financial Conflict of Interest policy for disclosure requirements for mutual funds since the Institutional policy may be more restrictive.

**What about stock and stock options? (Institution and Investigator)**

Please refer to your Institution's Financial Conflict of Interest policy. Stock option assets are to be reported by the time an application for funding is submitted, and then reported annually or as new stocks are obtained, in the same manner as all other assets. The documentation needed to determine the value of a stock option is defined by the Institution.

**Are foreign investments (e.g., shares in a foreign corporation) covered by the financial disclosure requirement? (Institution and Investigator)**

Maybe. Financial interests are defined as anything of monetary value, whether or not the value is readily ascertainable. Any financial interest that meets the definition of Significant Financial Interest under the regulation must be disclosed. Foreign investments are covered financial interests under the regulation, if the investments satisfy the definition of Significant Financial Interest. The Investigator must disclose Significant Financial Interests (and those of the Investigator's spouse and dependent children). Disclosure requirements and the documentation needed to determine the value of foreign investments should be defined by the Institution's Financial Conflict of Interest policy and procedures.

**What about "blind trusts?" Are those included in this final rule? (Institution and Investigator)**

Please refer to your Institution's Financial Conflict of Interest policy. Institutions may determine that the research will not be affected by qualified blind trust assets not known to the Investigator that are managed by an independent fiduciary. Because such assets would not be known to an Investigator, an Institution might determine that they could not directly and significantly affect the design, conduct or reporting of the research. Of course, an Investigator is aware of the assets originally placed in the trust at the time of its formation and would be required to disclose any such assets that would reasonably appear to be related to his/her

institutional responsibilities. The Institution may determine that only new assets purchased with the proceeds from the original assets would be unknown to the Investigator.

**Is income from royalties subject to this regulation? (Institution and Investigator)**

It depends. Financial interests are defined as anything of monetary value, whether or not the value is readily ascertainable. Royalties are potentially subject to disclosure, as are other interests related to intellectual property. Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the \$5,000 threshold as described in the preamble (page 53265). If the royalties paid to the Investigator (or his/her spouse and dependent children) satisfy the definition of "Significant Financial Interest," then they must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by the employing or appointing applicant or awardee Institution and are licensed or potentially licensed through the applicant or awardee Institution (i.e., they are not personally owned by the Investigator), they are considered remuneration from the Institution and would not be considered a Significant Financial Interest of the Investigator. Royalties received by the Investigator from the Institution would be excluded from the definition of Significant Financial Interest if the Investigator is currently employed or otherwise appointed by the Institution.

Unlicensed intellectual property that does not generate income is also excluded from the definition of Significant Financial Interest. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to the regulation. Disclosure requirements and the documentation needed to verify the value of royalties or agreements to share in royalties should be defined by the Institution's Financial Conflict of Interest policy and procedures. (See definition of Significant Financial Interest).

**Is an Investigator required to disclose all financial interests received from a foreign Institution of higher education or the government of another country? (Institution and Investigator)**

Yes. In each case when the regulation refers to exclusions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency, the reference is made to a United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

**Does an individual who participates as a subrecipient "Investigator" under a Phase I SBIR/STTR award need to disclose his/her significant financial interest to his/her Institution (e.g., University)? (Institution and Investigator)**

It depends. The requirement for an Investigator to disclose his/her significant financial interest (SFI) depends upon if the Investigator, at the subrecipient Institution, is a Public Health Service (PHS)-supported Investigator. If the subrecipient Investigator does not receive PHS funding, the Investigator would not be required to disclose his/her SFI to their Institution (e.g., University) unless it was a requirement of the Institution (e.g., University's FCOI policy). On the other hand, if the subrecipient Investigator is a PHS-funded Investigator, he/she must disclose his/her SFI in accordance with the 2011 Revised FCOI regulation.

**Does the regulation require the Investigator to keep up with day-to-day changes in value of publicly traded stock or other similar interests with fluctuating value? (Institution and Investigator)**

No. Generally, the annual disclosure requirement will be sufficient to allow the Investigator to disclose updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

**Is an Investigator required to disclose remuneration received in excess of \$5,000 from an outside entity for services performed (e.g., data analysis) when the payment is made directly to the Investigator's Institution. (Institution and Investigator)**

No. Since the payment for services is paid to the Institution, Investigator disclosure is not required. However, if payment for services is paid directly to the Investigator, the remuneration must be disclosed by the Investigator, no matter if the Investigator turns the money over to the Institution or if the money will be used to support the Investigator's future research activities.

**What must be disclosed by an Investigator who is employed by a for-profit company in which he/she has an equity interest? (Institution and Investigator)**

If the Investigator is supported by an NIH grant through a for-profit company (i.e., the for-profit company is the grantee), the Investigator would not need to disclose the equity interest to the for-profit company that is applying for, or that receives, NIH research funding because any ownership interest held by an Investigator in a commercial or for-profit organization is excluded from disclosure.

**Is an Investigator required to disclose his/her ownership interest in a for-profit or commercial organization when the Investigator is employed by a University? (Institution and Investigator)**

The answer to this question depends on which entity is applying for or receiving PHS-funded research.

University is the applicant/grantee: If the Investigator is supported by an NIH grant awarded to a University, the Investigator must disclose his/her Significant Financial Interest (SFI) (e.g., ownership interest or equity interest) to the University if the SFI is related to the Investigator's institutional responsibilities.

For-profit Company is the applicant/grantee: If the Investigator is supported by an NIH grant awarded to a for-profit/commercial organization, the Investigator's ownership interest in the company is not considered an SFI and is therefore exempt from disclosure.

Note that the Investigator's disclosure of his/her equity interest in a for-profit/commercial organization is only excluded (i.e., not considered an SFI) in those cases where the for-profit/commercial organization is the Institution that is applying for, or that receives, NIH research funding.

**What must an Investigator disclose for his/her first financial disclosure under the 2011 revised regulation related to intellectual property rights and interests? (Institution and Investigator)**

Upon the receipt of income, the Investigator is required to disclose the aggregated value of income received in excess of \$5,000 from the entity in the twelve months preceding the disclosure. Because this income is subject to the definition of "Significant Financial Interest," the following disclosure considerations apply:

- (1) Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research.
- (2) Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.
- (3) Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.

**If an Investigator receives a new royalty payment from the same source but for a different patent, is this considered a "new" Significant Financial Interest (SFI)? (Investigator and Institution)**

No. Since the nature of SFI and source of SFI is the same, the SFI is not considered "new". At the time of the annual disclosure, the Investigator must disclose the current aggregated value of the SFIs received over the previous 12 months so that the Institution can determine if any changes to an existing management plan are warranted. Any annual FCOI report would need to provide the status of the existing FCOI and any changes to the management plan resulting from the increase in value. (Also refer to FAQ D.9.)

**Must an Investigator disclose royalty payments received in the previous year from the same source for two different patents when the value of each payment is below \$5,000 but the aggregated value is in excess of \$5,000? (Investigator and Institution)**

Yes, at the time of the annual disclosure, the Investigator must disclose the aggregated value of the royalty payments to the Institution because the income received from the same source in the previous year exceeds \$5,000 and, therefore, represents a significant financial interest.

## **G. Public Accessibility**

### **Is the Institution required to make its policy on Financial Conflict of Interest publicly accessible? (Institution)**

Yes. The Institution is required to make its policy on Financial Conflict of Interest publicly 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.

When the Institution posts its Financial Conflict of Interest policy or otherwise makes the policy publicly accessible, it signifies that the Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements. The Institution must be in compliance with the 2011 revised regulation no later than August 24, 2012.

### **What are the requirements for making information on Financial Conflict of Interest of senior/key personnel publicly accessible? (Institution and Investigator)**

Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response within five business days of a request, of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

- . The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- A. The Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
- B. The Institution determines that the Significant Financial Interest is a **Financial Conflict of Interest.**

The information that the Institution makes available via a publicly accessible Web site or written response shall include, at a minimum, the following:

- iii. Investigator's name;
- iv. Investigator's title and role with respect to the research project;
- v. Name of the entity in which the Significant Financial Interest is held;
- vi. Nature of the Significant Financial Interest; and
- vii. 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.

Institutions have inquired about the need to include a contact person's name or provide a dedicated mailing address or email address where individuals can send in their written request for the information above. Although information beyond what is specified in the regulation is not required by NIH, Institutions may determine that designating a contact in this manner is a helpful step in satisfying their obligation to make the information publicly accessible.

### **When should information be updated when the Institution makes information available on a publicly accessible Web site? (Institution)**

If the institution uses a publicly accessible Web site for making the information publicly accessible, the information shall be updated at least annually. In addition, the Institution shall update the Web site within sixty (60) days of the Institution's receipt or identification of information concerning any additional Significant Financial Interests of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel; or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research, if the Institution determines that the Significant Financial Interest is related to the NIH-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, 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.

## **I. Retrospective Review and Mitigation Report**

### **What is a retrospective review and when is it required? (Institution)**

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 NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

## **L. Training Requirements**

### **Does the regulation require Investigator training? (Institution and Investigator)**

Yes. Each Investigator (as defined by the regulation), including subrecipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

Institutions may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements. However, Institutions must also provide additional training regarding Investigator's responsibilities for disclosure of Significant Financial Interests and of the Institution's specific policy on financial conflicts of interests.

### **When is an Investigator required to complete Financial Conflict of Interest training if they are currently funded under a NIH grant or cooperative agreement at the time the Institution's FCOI policy is implemented and posted? (Institution and Investigator)**

Institutions are expected to develop and implement their Financial Conflict of Interest policies during the 365-day implementation period provided in the 2011 revised regulation. Once the Institution implements and posts their Financial Conflict of Interest policy as required under the final rule, Investigators are expected to then complete required training prior to engaging in NIH-supported research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date.

### **Can an Institution implement the regulatory requirements prior to having all of its Investigators trained on Financial Conflict of Interest as required under the 2011 revised regulation? (Institution)**

Yes. The implementation date can precede the date when all Investigators have been trained. If the implementation date falls on the 365<sup>th</sup> day (i.e., August 24, 2012), it is expected that all Investigators who are supported by the NIH will complete their training obligations prior to

engaging in NIH-supported research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date.

**Institutions are required to train Investigators "immediately" upon certain situations. How is "immediately" defined in this context? (Institution)**

NIH expects Institutions to define "immediately" in the Institution's Financial Conflict of Interest policy, which would establish a reasonable timeframe when Investigators must complete training under the prescribed circumstances. Although the regulation does not define a precise timeline, the expectation is that Institutions will make it a priority to ensure Investigators understand and comply with the requirements of the regulation and the Institution's Financial Conflict of Interest policy, which reinforces the need for training to be handled expeditiously.