

Fraunhofer Institute for Digital Medicine MEVIS

FINANCIAL CONFLICT OF INTEREST POLICY

APPLICABLE TO A

SUBAWARD ISSUED UNDER A PUBLIC HEALTH SERVICES PRIME AWARD

I. Introduction

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of research at the Fraunhofer Institute for Digital Medicine MEVIS (the “*Institution*”), an unincorporated institute of Fraunhofer Society for the Advancement of Applied Research (*Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e. V.*), a not-for-profit research organization established and existing under the laws of Germany (“*FhG*”), and to comply with certain United States regulations.

The Public Health Service of the U.S. Department of Health and Human Services (as further defined below, “*PHS*”), which includes the U.S. National Institutes of Health, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control, has adopted regulations on promoting objectivity in research. These regulations (the “*PHS-regulations*”), which include in particular 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94, describe the actions an individual and an organization must take in order to promote objectivity in research. The regulations apply to all PHS funded grants, cooperative agreements, research or other contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants), and applications or proposals for such grants, agreements and contracts, and subawards where the originating sponsor providing the funding is the PHS or a PHS Awarding Component (as that term is defined below).

These PHS-regulations require that investigators at the Institution submitting proposals or applications for funding, on behalf of a subrecipient, where the prime sponsor is the PHS, prior to the submission of the subaward application or proposal to the PHS Grantee (as defined below), disclose to Institution any significant financial interests related to their institutional responsibilities at the Institution.

For purposes of this policy a “*PHS Grantee*” is the entity or organization, whether a U.S. domestic or a foreign, public or private, entity or organization (but excluding a United States federal agency) that is applying for, or that receives a prime award from the PHS or any PHS Awarding Component (as that term is defined below) or that enters into a contract with PHS or any PHS Awarding Component (and provides property or services under such contract for the direct benefit or use of the United States federal government) or that submits a proposal for such contract, and, under that prime award of PHS research funding or contract, the PHS Grantee issues a subaward to the Institution (or to FhG for use by the Institution) as the subrecipient. References to prime award include, as applicable, the prime award or a contract between PHS or a PHS Awarding Component and the PHS Grantee, and references to subaward include, as applicable the subaward from the PHS Grantee to the Institution (or FhG for use by the Institution) as the subrecipient or the (sub)contract between the PHS Grantee and the Institution (or FhG for use by the Institution) as the subcontractor.

This policy has been developed to comply with the above-referenced specific U.S. federal agency requirements and regulations, which were promulgated to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of PHS-funded

research, including research funded under National Institutes of Health (NIH) grants or cooperative agreements, will be free from bias resulting from investigator financial conflicts of interest.

This policy governing financial conflict of interest applies to all Investigators (as defined below) at the Institution. However, to the extent, any Research that is funded by PHS, including as part of any subaward from the PHS Grantee, is conducted at any other institute or department or division of FhG or any Investigator works at any other institute or department or division of FhG, this policy shall also apply to such other institute or department or division of FhG, and the term “**Institution**” as used in this policy is expanded accordingly.

The Institutional Official (as defined below) is responsible for ensuring implementation of this policy on behalf of the Institution and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may constitute cause for disciplinary or other administrative action pursuant to the policies of the Institution or FhG.

II. Certain Definitions

In addition to the capitalized terms defined above and elsewhere in this policy, the following capitalized terms, whether used in the singular or the plural, as used in this policy have the meaning set forth below:

“**Equity Interest**” includes any share of capital stock, any interest in any limited liability company, any partnership interest, as well as any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

“**Family**” means any member of an Investigator’s immediate family, specifically, any dependent children and spouse.

“**Financial Interest**” means, subject to the exceptions specifically identified below, anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: (i) salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); (ii) any Equity Interests (e.g., stocks, stock options, or other ownership interests); and (iii) intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

“**Financial Conflict of Interest**” means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-funded Research, including under any subaward. As used in this policy, the terms “**design**,” “**conduct**” and “**reporting**” are to construed broadly and generally also include the analysis, management and administration, and distribution of such Research.

“**Significant Financial Interest**” means a Financial Interest (1) that may reasonably appear to be related to an Investigator’s Institutional Responsibilities, and (2) that consists of one or more of the following interest(s) of such Investigator or any member of the Investigator’s Family:

- a) with regard to a publicly traded entity, the aggregate value of any salary or other payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) or other remuneration from the entity during the 12-month period preceding the disclosure, and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds U.S.\$5,000 (or the equivalent in other currencies, such as Euros, as calculated below); or

- b) with regard to a non-publicly traded entity, the aggregate value of any salary or other payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) or any other remuneration, received from the entity during the 12-month period preceding the disclosure, when aggregated, exceeds U.S.\$5,000 (or the equivalent amount in other currencies, such as Euros, as calculated below); or
- c) with regard to a non-publicly traded entity, an Equity Interest of any value; or
- d) intellectual property rights and interests (e.g., patents, trademarks, service marks, copyrights), upon receipt of income related to such rights and interests, or
- e) any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator or any member of his or her Family and not reimbursed to the Investigator (or any member of his or her Family) so that the exact monetary value may not be readily available).

For purposes of this policy, in order to exchange an amount in U.S. dollars into Euros, or another currency, the exchange rate published by the European Central Bank on the business day immediately preceding the end of the relevant period applies.

For Investigators, a “**Significant Financial Interest**” also includes any reimbursed or sponsored travel undertaken by the Investigator and/or any member of the Investigator’s Family and related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator and/or Investigator’s Family as well as such travel that is reimbursed, even if the exact monetary value is not readily available; provided that “**Significant Financial Interest**” excludes travel reimbursed or sponsored by United States Federal, state or local governmental agencies, United States institutions of higher education (as defined at 20 U.S.C. 1001(a)), any United States research institute affiliated with any such United States institution of higher education, any United States academic teaching hospital, and any United States medical center.

“**Significant Financial Interest**” does not include:

- a) salary, royalties, or other remuneration paid by the Institution (or FhG on behalf of or for the benefit of the Institution) to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution or by FhG on behalf of or for the benefit of the Institution, including intellectual property rights assigned to the Institution or FhG and agreements to share in royalties related to such rights;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by United States federal, state or local governmental agencies; United States institutions of higher education as defined at 20 U.S.C. 1001(a); any United States research institute affiliated with any such United States institutions of higher education; any United States academic teaching hospital; or any United States medical center;
- d) income from service on advisory committees or review panels for United States federal, state or local governmental agencies; United States institutions of higher education as defined at 20 U.S.C. 1001(a); any United States research institute affiliated with any such United States institutions of higher education, United States academic teaching hospitals; or United States medical centers; and

- e) income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

“Institutional Official” means the individual, within the Institution and designated by the Institution, who is responsible for the solicitation and review of disclosures of Significant Financial Interests of each Investigator that is planning to participate in, or is participating in, any PHS-funded Research, including pursuant to any subaward under the prime award from the PHS Grantee, including those of the Investigator’s Family. For the purposes of this policy, the initial Institutional Official designated by the Institution shall be **Dipl.-Betw. Thomas Forstmann**, who works at the Institution. The Institution (or FhG acting on behalf of the Institution) may replace the Institutional Official at its convenience, in which case such replacement official shall act as the Institutional Official for purposes of this policy.

“Institutional Responsibilities” means the Investigator’s professional responsibilities on behalf of the Institution, such as, for example, research, teaching, clinical care and activities, administration, and institutional, internal and external professional committee service. These include:

- a) Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research) and research consultation;
- b) Externally sponsored or funded research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results) and professional services, such as sponsored by industry participants, government agencies or organizations, or other third parties;
- c) Lectures, teaching, and academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- d) Clinical service activities such as performing services for a university’s faculty;
- e) Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards, participation in department activities or faculty advisory boards, etc.; or
- f) Special service activities on behalf of Institution.

“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 a subaward under the prime award awarded to the PHS Grantee, or proposed for such funding, which may include, for example, collaborators or consultants, as appropriate. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal or contract and may include without limitation postdoctoral associates, senior scientists, or graduate students. The project director or principal Investigator, upon consideration of the individual’s role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the Research, and who qualifies as an Investigator under this definition. Upon request by Institution the principal Investigator will certify to the Institution each person who qualifies as an Investigator under this definition.

“Public Health Service” or **“PHS”** means the Public Health Service of the U.S. Department of Health and Human Services (**“HHS”**), and any components of such Public Health Service to which the authority involved may be delegated, including the National Institutes of Health. The component of the Public Health

Service that awards a prime award or contract is referred to as the “**PHS Awarding Component.**” The components of such Public Health Service to which the authority involved may be delegated include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

“**Research**” means a systematic investigation, study, or experiment designed to 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 policy, “**Research**” includes any such activity which is funded or for which funding is available under the prime award to the PHS Grantee from a PHS Awarding Component through a grant (such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award) or cooperative agreement or other contract or which is funded or for which funding is available under the subaward to Institution as the subrecipient from the PHS Grantee.

III. Conflicts of Interest

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to Research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited.

Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy.

If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

The Institution, through the Institutional Official, will inform each Investigator of this policy, the Investigator’s responsibilities regarding disclosure of Significant Financial Interests, and the PHS-regulations.

A. Disclosure of Significant Financial Interests

Prior to the submission of an application to the PHS Grantee for funding, each Investigator at the Institution must have disclosed to the Institutional Official an up-to-date listing of such Investigator’s and his or her Family’s Significant Financial Interests. Any new Investigator, who, subsequent to the submission of an application to the PHS Grantee for funding from the PHS Grantee, or in the course of the PHS-funded Research, including under the subaward to Institution, plans to participate in such Research, must similarly disclose such Investigator’s and his or her Family’s Significant Financial Interests to the Institutional Official promptly and prior to participation in the Research project.

1. Annual Disclosures

Each Investigator who is participating in PHS-funded Research, including under a subaward where the prime award originates from a PHS Awarding Component, must disclose his or her and his or her Family’s Significant Financial Interests to the Institution, through the Institutional Official, at least annually during

the period of the prime award and subaward, including by updating any prior disclosures. All completed disclosure forms must be submitted to the Institutional Official or his or her designee by March 1 for the previous calendar year, whether or not the Investigator has a Significant Financial Interest to disclose.

Any updated disclosures must include any information that was not disclosed initially to the Institution, pursuant to this policy, or in a subsequent disclosure of Significant Financial Interests (e.g., any Financial Conflict of Interest identified on a PHS-funded project directly as a PHS Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest).

2. Ad Hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. Each Investigator must disclose his or her and his or her Family's Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of his or her initial appointment or employment.

Prior to commencing any PHS-funded Research, including as a subrecipient, or applications for PHS-sponsored Research or submission of contract proposals, including as a subrecipient, where the Investigator or his or her Family has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her or his or her Family's Significant Financial Interests. The Institution will not submit a proposal or application, including as a subrecipient, unless each such Investigator has submitted any such ad hoc disclosure to the Institutional Official.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring (e.g., through purchase, contract, marriage, or inheritance) the new Significant Financial Interest.

3. Travel

Each Investigator must also disclose reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and/or the Investigator's Family) related to his or her Institutional Responsibilities if such reimbursed or sponsored travel constitutes a Significant Financial Interest (as defined above).

Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed or a determination of such monetary value) to determine whether the travel constitutes a Financial Conflict of Interest with the PHS-funded Research.

B. Review and Decision of the Institutional Official

The Institutional Official is responsible for the distribution, receipt, processing, review and retention of Significant Financial Interest disclosure forms.

If the disclosures as disclosed on the disclosure form by an Investigator reveals a Significant Financial Interest, the Institutional Official or his or her designee will promptly review such disclosure for a determination as to whether or not a Financial Conflict of Interest exists based on such disclosures.

The Institutional Official or his or her designee will review any Significant Financial Interest that has been identified in a disclosure to determine if the Significant Financial Interest is related to PHS-funded Research, including under a subaward from the PHS Grantee under the PHS prime award, and, if so, whether the Significant Financial Interest creates a Financial Conflict of Interest related to that PHS-funded Research, including under a subaward from the PHS Grantee under the PHS prime award.

The Institutional Official may involve the Investigator in the his or her determination of whether a Significant Financial Interest is related to the PHS-funded Research. The Institutional Official may also consult with legal counsel in making the determination.

If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the Financial Conflict of Interest, including the reduction or elimination of the conflict, as appropriate. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan.

For purposes of this policy, to “manage” a Financial Conflict of Interest means to take action to address the 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.

The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-funded Research, including under a subaward, goes forward.

Prior to the Institution’s expenditure of any funds under a PHS-funded Research project, including under a subaward, the Institutional Official will (1) review all Investigator disclosures of Significant Financial Interests, (2) determine whether any Significant Financial Interests relate to PHS-funded Research, (3) determine whether a financial conflict of interest exists, and, if so, develop and implement a management plan that will specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest.

The Institutional Official will also periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

Whenever, in the course of an ongoing PHS-funded Research project, including under a subaward, 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 Institutional Official will, within sixty (60) days, (1) review the disclosure of the Significant Financial Interest; determine whether it is related to PHS-funded Research, including under a subaward, and (2) determine whether a Financial Conflict of Interest exists, and, if so, implement, on at least an interim basis, a management plan that will 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, the Institutional Official 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 Institutional Official’s review, in which case the Institutional Official will implement these interim measures and the Investigator and the other Investigators, including the principal investigator and/or project director, will comply with these measures.

C. Guidelines for Determining “Relatedness” and Financial Conflict of Interest

The Institutional Official will determine whether an Investigator’s Significant Financial Interest is related to PHS-funded Research, including under a subaward from the PHS Grantee under a PHS prime award, and, if so related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest.

An Investigator’s Significant Financial Interest is related to the PHS-funded Research, including under the subaward, when the Institution, through the Institutional Official, reasonably determines that (i) the Significant Financial Interest could be affected by the PHS-funded Research, including as conducted under the subaward; or (ii) the Significant Financial Interest is in an entity whose financial interest could be affected by the Research.

A Financial Conflict of Interest exists when the Institution, through the Institutional Official, reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research, including under a subaward.

In determining whether an Investigator’s Significant Financial Interest is related to the PHS-funded Research, including under a subaward from the PHS Grantee under a PHS prime award, and if so, whether the relationship creates a Financial Conflict of Interest, the Institutional Official will consider the role of the Investigator and the opportunity (if any), to bias the results, the nature of the PHS-funded Research being proposed or conducted, including under a subaward, and the value of the Significant Financial Interest. In addition, the Institutional Official may also consider the following factors:

- a) Whether the Research is of a basic or fundamental nature directed at understanding basic scientific processes;
- b) Whether the degree of replication and verification of Research results is such that immediate commercialization or clinical application is not likely;
- c) Whether the goal of the Research is to evaluate an invention linked to the Significant Financial Interest (such as where the Significant Financial Interest is a patent, or an interest in a company or other entity that has licensed the invention);
- d) Where the Research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
- e) Where the Significant Financial Interest is in a privately held company or other entity, whether the Investigator’s Significant Financial Interest could result in the Investigator having influence over company or other entity decisions, or whether the Research could have a significant impact on the company’s or other entity’s business or financial outlook (excluding Phase I SBIRs and STTRs);
- f) The magnitude of the Significant Financial Interest(s) (e.g., the amount of consulting, or the percentage or value of equity);
- g) Where the Significant Financial Interest is in the sponsor of the Research, and the sponsor is a licensee of the Investigator’s or Institution’s technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future;

- h)** The number and nature of relationships an Investigator has with an entity, as multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts;
- i)** Whether the goal of the Research is to validate or invalidate a particular approach or methodology that could affect the value of the Significant Financial Interest;
- j)** Whether other scientific groups are independently pursuing similar questions;
- k)** Whether sufficient external review of the Research conducted and the reporting of Research results exist to mitigate undue bias;
- l)** Whether the goal of the Research project is a comparative evaluation of a technology in which an Investigator has a Significant Financial Interest; or
- m)** Whether the project involves a subaward to an entity in which the Investigator has a Significant Financial Interest.

D. Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a Financial Conflict of Interest exists, the Institutional Official will manage the Financial Conflict of Interest. The Institutional Official will determine by what means – such as the applicable Investigator’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by the Institutional Official or a committee created by the Institution – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the Institutional Official will be guided by the principles discussed in this policy. The Institutional Official will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the Research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:

- a)** Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the Research);
- b)** For research projects involving human subjects Research, disclosure of Financial Conflicts of Interest directly to human participants;
- c)** For research projects involving human subjects Research, use of a data and safety monitoring board;
- d)** 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;
- e)** Modification of the Research plan;
- f)** Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;

- g) Reduction or elimination of the Financial Interest (e.g., sale of an Equity Interest);
- h) Severance of relationships that create Financial Conflicts of Interests;
- i) Double-blind conditions;
- j) Written disclosure of the conflict to all individuals working on the Research project;
- k) Annual reports on the Research progress to the Institutional Official.

Whenever the Institution implements a management plan to manage a Financial Conflict of Interest, the Institutional Official will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project, including the subaward thereunder.

If the Institutional Official determines that a Financial Conflict of Interest exists, the Institutional Official will communicate his or her determination and the means the Institutional Official has identified for eliminating or managing the conflict, in writing, to the Investigator, to the relevant principal investigator/project director, and the appropriate direct supervisor. The Institutional Official will keep a record of the disclosure and other relevant information for at least three years as further provided in this policy. If the Institutional Official prescribes monitoring of the activity, the Institutional Official will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a subaward supported by a PHS prime award will be permitted until the Investigator has complied with the disclosure requirements of this Policy and has agreed, in writing, to comply with any management plans determined by the Institutional Official necessary to manage the Financial Conflict of Interest. The Institutional Official will communicate, in writing, with the PHS Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the PHS Grantee has reported the Financial Conflict of Interest to PHS (or the PHS Awarding Component). The PHS Grantee will notify the Institution when it may incur expenditures.

The Institutional Official will keep a record of Investigator disclosures of financial interests and the Institutional Official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years as provided in this policy and in accordance with the terms and conditions of the subaward and relevant PHS-regulations.

E. Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of funds under a PHS-funded Research project, including under a subaward, by the Institution, the Institution will ensure public accessibility, via a publicly accessible Internet website of the Institution or by written response to any requestor within five (5) business days of a request, of information concerning any Significant Financial Interest disclosed that meets the following three criteria:

- a) The Significant Financial Interest was disclosed and is still held by senior or key personnel;
- b) A determination has been made by Institution that the Significant Financial Interest is related to the PHS-funded Research, including Research funded through a subaward thereunder; and
- c) A determination has been made by Institution that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the applicable requirements of the PHS-regulations.

For purposes of this policy, “**senior or key personnel**” means the project director and/or principal investigator of a PHS-funded Research project and any other person identified as senior or key personnel by the Institution in the grant application, subaward application, subaward, progress report, or any other report submitted to the PHS or PHS Grantee by the Institution and any other personnel as essential to work performance and identified as key personnel in the contract proposal and contract with the PHS Grantee or any PHS Awarding Component.

The information that the Institution will make available via a publicly accessible Web site or in a written response to any requestor within five (5) days of request will include, at a minimum, the following:

- a) The Investigator’s name;
- b) The Investigator’s title and role with respect to the Research project;
- c) The name of the entity in which the Significant Financial Interest is held;
- d) The nature of the Significant Financial Interest; and
- e) The approximate dollar value of the Significant Financial Interest (or the equivalent amount in other currencies, such as Euros, as calculated herein) in the following ranges: \$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.

If the Institution uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty (60) days of receipt or identification of information concerning any additional Significant Financial Interest of the senior or key personnel for the PHS-funded Research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior or key personnel new to the PHS-funded Research project, if it is determined by the Institutional Official that the Significant Financial Interest is related to the Research and is a Financial Conflict of Interest.

If the Institution responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and 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 sixty (60) days of the Institution’s identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor.

Information concerning the Significant Financial Interests of an individual, as limited by this policy, will remain available, for responses to written requests or for posting via the Institution’s publicly accessible Web site for at least three (3) years from the date that the information was most recently updated.

IV. Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS- funded Research project, including a subaward from the PHS Grantee that is funded by a PHS prime award, the Institution will provide to the PHS Grantee a

Financial Conflict of Interest report compliant with PHS-regulations regarding any Investigator's Significant Financial Interest found by the Institutional Official to be conflicting and will ensure that the Institution has implemented the corresponding management plan. The Institution may not incur expenditures until it has received notification to do so from the PHS Grantee. Institution will provide such report to the PHS Grantee with sufficient time to enable the PHS Grantee to provide timely Financial Conflict of Interests reports, as necessary, to the PHS Awarding Component. However, in cases in which the Institutional Official identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, including under a subaward, the Institution will not be required to submit a report on such Financial Conflict of Interest to the applicable PHS Grantee, unless required to do so under the subaward agreement with the PHS Grantee.

While the subaward is ongoing (including any extensions with or without funds), Institution will provide to the PHS Grantee an annual Financial Conflict of Interest report that addresses the status of the Financial Conflict of Interest and any changes in the management plan. Institution will provide each such report to the PHS Grantee with sufficient time to enable the PHS Grantee to provide timely Financial Conflict of Interests reports, as necessary, to the PHS Awarding Component.

For any Significant Financial Interest that is identified by the Institutional Official as conflicting subsequent to an initial Financial Conflict of Interest report during an ongoing PHS-funded Research project (e.g., upon the participation of an Investigator who is new to the Research project, including under the subaward), Institution will provide to the PHS Grantee, within forty-five (45) days following disclosure of such subsequently identified conflicting Significant Financial Interest to the Institutional Official, an Financial Conflict of Interest report regarding such Financial Conflict of Interest and ensure that Institution has implemented a management plan and the Investigator has agreed to the relevant management plan.

Any Financial Conflict of Interest report required to be submitted to the PHS Grantee under this Section will include sufficient information to enable the PHS Grantee to understand the nature and extent of the Financial Conflict of Interest, and to assess the appropriateness of the Institution's management plan. Elements of the Financial Conflict of Interest report will include the project or contract number, project title, the principal investigator or project director (or the contact principal investigator or project director if a multiple principal investigator or project director model is used), name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium), the U.S. dollar value of the Financial Interest in the following ranges (which may be based on the equivalent amount in other currencies, such as Euros, as calculated herein): \$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, a description of how the Financial Interest relates to the PHS-funded Research, including the subaward thereunder, and the basis for the Institution's determination that the Financial Interest conflicts with such Research, and a description of the key elements of the Institution's management plan, including: (1) role and principal duties of the conflicted Investigator in the Research project; (2) conditions of the management plan; (3) how the management plan is designed to safeguard objectivity in the Research project; (4) confirmation of the Investigator's agreement to the management plan; (5) how the management plan will be monitored to ensure Investigator compliance; and (6) other information as needed.

For any Financial Conflict of Interest previously reported by the Institution with regard to an ongoing PHS-funded Research project, including any subaward thereunder, the Institution will provide to the PHS Grantee an annual Financial Conflict of Interest 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, including any subaward thereunder. The annual Financial Conflict of Interest report will specify whether

the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. The Institution will provide annual Financial Conflict of Interest reports to the PHS Grantee for the duration of the project period (including extensions (with or without funds)), including during the subaward thereunder, in the time and manner specified by the PHS Grantee.

V. Training

Each Investigator must complete training on this policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in Research related to any PHS-funded subaward or prime award received by the PHS Grantee and at least every four years, and immediately when any of the following circumstances apply:

- 1) The Institution revises or amends this policy, or procedures related to this policy, in any manner that affects the requirements of Investigators, and such training is to be completed within the timeframe specified in communications announcing such changes;
- 2) such Investigator is new to the Institution's Research under a subaward issued under a PHS prime award, and such training is to be completed prior to his or her participation in the Research; or
- 3) such Investigator is not in compliance with this policy or a management plan issued under this policy, as so determined by the Institution through the Institutional Official or a committee established by the Institution, and such training is to be completed within 30 days in the manner specified by the Institutional Official.

Institution requires its Investigators to watch and complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> as well as Institution's own training course on this policy, and the Investigator's responsibilities regarding disclosure and the PHS-regulations, which will be made available by the Institutional Official. Each Investigator must sign written certifications of completion at the end of each training, submit each such certification to the Institutional Official, and retain it for audit purposes.

VI. Failure to Comply with this Policy

No expenditures of funds on a subaward supported by a PHS prime award will be permitted unless each Investigator has complied with the disclosure requirements of this policy and has agreed, in writing, to comply with any management plan for a Financial Conflict of Interest approved by the Institutional Official.

Whenever the Institution identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institutional Official during an ongoing PHS-funded Research project, including a subaward thereunder, the Institutional Official will, within sixty (60) days (1) review the Significant Financial Interest, (2) determine whether it is related to PHS-funded Research, including under a subaward, and (3) determine whether a Financial Conflict of Interest exists; and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest going forward.

If the failure of an Investigator to comply with this policy or a Financial Conflict of Interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, including under a subaward of a prime award to the PHS Grantee, the Institution shall promptly notify the PHS Grantee of the corrective action taken or to be taken.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination of employment, and termination of the subaward by the PHS Grantee.

A. Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official, on behalf of the Institution and FhG, may suspend all relevant activities or take other disciplinary and other administrative action to ensure Investigator compliance as appropriate until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional Official's decision to take disciplinary or administrative action against an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, and will notify the individual of the right to appeal the decision.

Institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the Research is made available from the PHS Grantee, such notification shall be made promptly to the PHS Grantee for reporting to PHS and the PHS Awarding Component. Institution may also enforce any applicable corrective actions that may be required by PHS or the PHS Awarding Component or required by PHS Grantee pursuant to the subaward.

B. Retrospective Review

If the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including, but not limited to, an Investigator's failure to disclose a Significant Financial Interest that is determined by the Institutional Official to be a Financial Conflict of Interest, or, a failure by the Institution or a second tier subrecipient to timely review or manage or report a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest approved by the Institutional Official, the Institutional Official (or a committee appointed by the Institutional Official) will, within 90 days of the Institutional Official's determination of noncompliance:

- 1) complete a retrospective review of the Investigator's activities and the PHS-funded Research project, including the subaward thereunder, to determine whether any PHS-funded Research, including under any subaward, or any portion thereof, conducted during the period of non-compliance was biased in the design, conduct or reporting of such Research;
- 2) Document the retrospective review consistent with the applicable PHS-regulations. Documentation of the retrospective review will include the project number, project title, the principal investigator or project director (or the contact principal investigator or project director if a multiple principal investigator or project director model is used), name of the Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed), and the findings of the review, and the conclusions of the review. In addition, the documentation of the Institution will include the determination as to whether any Research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this policy or a Financial Conflict of Interest management plan, was biased in the design, conduct or reporting of the Research. This retrospective review will be completed in the manner and

within the time frame established by PHS-regulations and the terms and conditions of the subaward agreement.

- 3) Notify the PHS Grantee in writing. The Institutional Official will update any previously submitted report to the PHS Grantee as the prime PHS-awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the Institution will promptly notify the PHS Grantee and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify the elements documented in the retrospective review, a description of the impact of the bias on the Research project and the Institution's plan of action and 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 shall submit Financial Conflict of Interest reports annually to the PHS Grantee as the prime PHS awardee, in accordance with the applicable PHS-regulations and terms and conditions of the subaward agreement. Depending on the nature of the Financial Conflict of Interest, the Institutional Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the Research project, including the subaward thereunder, between the date that the Financial Conflict of Interest is identified and the completion of the Institutional Official's retrospective review, in which case the Institutional Official will implement these interim measures and the Investigator and the other Investigators, including the principal investigator and/or project director, will comply with these measures.

C. Clinical Research

If the PHS Grantee or the HHS determines that a PHS-funded project of clinical Research, including under a subaward, 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 policy or the applicable PHS-regulations, the Institution will 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, and such Investigator agrees to comply with these requirements.

VII. Record Retention

The Institutional Official will retain and maintain 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 this policy and any retrospective review, if applicable, including all conflict management plans, and all related documents and records, for a period of three years from the latter of the date the final expenditure report is submitted to the PHS Grantee and the date of final payment or, where applicable, from other dates specified in 45 C.F.R. 74.53(b), 45 C.F.R. 92.42 (b), or, if applicable, for the time periods specified in 48 C.F.R. part 4, subpart 4.7, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period (or other applicable period), in which case all these records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

VIII. Confidentiality

To the extent permitted by law, all records under VII. above will be confidential. However, Institution and FhG may be required to make such information available to the a PHS Grantee, a PHS Awarding Component and/or HHS, to a requestor of information concerning Financial Conflict of Interest related to PHS funding or to the primary entity who made the funding available to Institution, if requested or required. The Institution or FhG may, promptly upon such request, make available such records and related information, including as relating to an 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. To the extent required by applicable law, the PHS-regulations, or the applicable subaward agreement, the Institution or FhG may submit, or permit on site review of, all records pertinent to compliance with this policy, the PHS-regulations, or the applicable subaward agreement.

If the Institution or FhG is requested to provide any such records to any outside entity or agency with respect to an Investigator or his or her Family, such Investigator will be informed of any such disclosures in response to such request.

IX. Regulatory Authority

This policy implements the requirements and regulations of 42 C.F.R. 50 Subpart F and 45 C.F.R. 94 of the United States Code of Federal Regulations. Where there are substantive differences between this policy and these requirements or regulations, the regulations and requirements shall take precedence.