

Leibniz Institute for Prevention Research and Epidemiology – BIPS GmbH (BIPS)

Financial conflict of interest (FCOI) policy

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1. Introduction

The United States Department of Health and Human Services (HHS) developed the regulations at [42 CFR part 50 subpart F](#), "Promoting Objectivity in Research" and [45 CFR part 94](#) "Responsible Prospective Contractors" to promote objectivity in Public Health Service (PHS) funded Research for grants, cooperative agreement and research contracts, respectively. The regulations were first published in 1995 and revised the regulations in 2011. This policy implements the requirements of the 2011 revised FCOI regulation for grants and cooperative agreements.

The regulations apply to all National Institutes of Health (NIH) applications and funded grants, cooperative agreements, and research contracts, excluding the Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and/or awards.

The implementation of the regulation, through the issuance of this policy, establishes standards that provide a reasonable expectation that the design, conduct and reporting of PHS/NIH-funded projects will be protected from bias resulting from an Investigator's Financial Conflict of Interest (FCOI). This policy also serves to protect the safety of animals and human research participants, the reputation of the recipient Institution and of the "Investigator" who participates in PHS/NIH- funded Research. These requirements also work together to preserve the public's trust that the Research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards.

2. Applicability

This policy implements the regulatory requirements provided in [42 CFR part 50 subpart F](#) for grants and cooperative agreements issued by the NIH. The policy also applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in or who participate in NIH-funded Research.

3. Definitions

For the purpose of these policies and procedures, the following definitions apply:

- **Designated Official (DO):** The head of the Subdivision Compliance & General Administration is responsible at BIPS to oversee the Financial Conflicts of Interest process, including solicitation and review of disclosures of Significant Financial Interests, identification of FCOIs per the regulatory criteria provided in [42 FCR 50.604\(f\)](#), and monitoring staff FCOI training requirements.
- **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.
- **Financial Interest (FI):** Anything of monetary value, whether or not the value is readily ascertainable.
- **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, Public Health Service (e.g., NIH) funding.
- **Institutional Responsibilities:** Professional activities an Investigator performs on behalf of the Leibniz Institute for Prevention Research and Epidemiology – BIPS GmbH (BIPS) including research, development, publication, dissemination and transfer activities, consulting, technical services, research services, administration, committee memberships, or any other duties defined by their roles as employee.

- **Investigator:** The project director (PD) or principal investigator (PI) and any other person, regardless of title and position, who is responsible for the design, conduct, or reporting of research funded by an award or proposed funding, which may include collaborators or consultants. BIPS will consider the individual's role, rather than title, and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the PHS-funded Research.
- **NIH:** The biomedical research agency of the PHS.
- **PHS:** 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-Funded Research:** Any activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under PHS Act or statutory authority.
- **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, proceeding article, book, or book chapter) and product development (e.g., an intervention, a digital application, software). As used in the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.
- **Senior/Key Personnel:** The PD/PI and any other person identified as senior/key personnel by BIPS in the award application, progress report, or any other report submitted to the NIH. *This term is defined only as it relates to the public accessibility requirements described under Section 9.*
- **Significant Financial Interest (SFI):**
 - 1) **A domestic or foreign** financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner, and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities (research, development, publication, consulting, technical services, research services, administration, committee memberships, or any other duties defined by their roles as employee of BIPS performed on behalf of BIPS:
 - i. **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 USD 5,000 (or, throughout, an equivalent value in another currency at the time the remuneration is received). 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. **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 USD 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).
 - iii. **Intellectual Property Rights and Interests:** A significant financial interest exists upon receipt of income greater than USD 5,000 received over the preceding months that is related to such rights and interests (e.g., patents, copyrights).
- 2) Investigators must disclose the occurrence of any **reimbursed or sponsored travel** that exceeds USD 5,000 (i.e. 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. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- The disclosure requirement does not apply to travel reimbursed or sponsored by the following:
- i. A federal, state, or local government agency located in the United States,
 - ii. A United States institution of higher education,
 - iii. An academic teaching hospital,
 - iv. A medical center, or
 - v. A research institute affiliated with a United States institution of higher education.
- 3) The term 'significant financial interest' does **not** include, and therefore Investigators are not required to disclose, the following types of Financial Interests:
- i. Salary, royalties, or other remuneration paid by BIPS/the University of Bremen to the Investigator if the Investigator is currently employed or otherwise appointed by BIPS including intellectual property rights assigned by BIPS and agreements to share in royalties related to such rights.
 - ii. 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.
 - iii. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.
 - iv. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

- **NOTE: Exclusions above do not apply to non-U.S. Financial Interests:** Investigators must disclose all non-U.S. Financial Interests (including income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any non-U.S. entity, including non-U.S. Institutions of higher education or a non-U.S. government (which includes local, provincial, or equivalent governments of another country than the U.S.) other than BIPS/the University of Bremen when such income meets the threshold for disclosure (e.g., income in excess of USD 5,000).

4. Significant Financial Interest disclosure requirements for Investigators

Investigators will disclose their SFIs that are related to their '*institutional responsibilities*' as defined in the policy.

The disclosure will not be limited to an Investigator's research responsibilities or their funded Research as this is too narrow in scope and not consistent with the 2011 regulation.

The Investigator SFI disclosures will be retained by the Institution as part of the record maintenance requirements.

Investigators will disclose their SFIs at the following times:

- **At the time of application:** The principal investigator and all other individuals who meet the definition of '*Investigator*' must disclose their SFIs to BIPS's Designated Official. Any new Investigator who, after applying for NIH funding or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the Designated Official promptly and prior to participation in the project.
- **Annually:** Each Investigator participating in research under an NIH award must submit an updated disclosure of SFI at least annually (on or before December 31), during the period of the award. The annual disclosure must include any information not disclosed initially to BIPS pursuant to this FCOI policy or in a subsequent disclosure of SFI (e.g., any Financial Conflict of Interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- **Ad hoc basis - new SFIs during the award:** Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

5. Review of SFI disclosures by the BIPS' Designated Official

The Designated Official (DO) will conduct reviews of SFI disclosures. The DO will review any SFI identified in a disclosure and compare these interests to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the Research to determine if the SFI is related to the PHS/NIH-funded Research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award as explained in Section 6.

The SFI disclosures will be reviewed as described below:

- **Prior to the expenditure of awarded funds (e.g., during the just-in-time stage):** The Designated Official will review the Investigator's SFI(s) prior to the NIH issuing a new award. If an FCOI is identified, BIPS will submit an FCOI report to the NIH via the eRA Commons FCOI module prior to the expenditure of funds under the new award.
- **Annual disclosure:** The annual disclosure will require the Investigator to disclose updated values of any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest). The Designated Official will review the Investigator's annual disclosure and use the updated information to determine if any changes are needed to an existing management plan. Any changes to an existing management plan will be reported to the NIH when the next annual FCOI report is due, if applicable.
- **Ad hoc basis - new SFIs during award period:** Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the Designated Official will, **within 60 days** review the disclosure of SFI, determine whether the SFI is related to the NIH-funded Research, determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI. An FCOI will be submitted to the NIH within 60 days of identifying the FCOI as described in section 10.

6. Guidelines for determining 'relatedness' of SFI to PHS/NIH-funded Research and a Financial Conflict of Interest

The Designated Official will determine whether an Investigator's SFI is related to the Research under an NIH award and, if so, whether the SFI is a Financial Conflict of Interest.

- **Relatedness test:** An Investigator's SFI is related to the Research when the Designated Official reasonably determines the SFI:
 - 1) Could SFI be affected by the PHS/NIH-funded Research; or
 - 2) Is SFI in an entity whose Financial Interest could be affected by the PHS/NIH-funded Research.

Investigator involvement: The Designated Official may involve the Investigator in determining whether an SFI is related to the NIH-funded Research.

- **FCOI determination:** A financial conflict of interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. 'Significantly' means that the financial interest would have a material effect on the research.

7. Management of Significant Financial Interests that pose Financial Conflict of Interest

If a Financial Conflict of Interest exists, the Designated Official will determine what management conditions and/or strategies will be put in place to manage the FCOI. Examples of conditions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:

- Public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);

- For research projects involving human subjects Research, disclosure of Financial Conflicts of Interest directly to human participants in the informed consent document;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- Reduction or elimination of the Financial Interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts.

If the Designated Official determines that a conflict exists, it will communicate its determination and the means developed for managing the FCOI in writing to the individual.

No expenditures on an NIH award will be permitted until the Investigator has complied with the disclosure requirements of this FCOI policy and has agreed, in writing, to comply with any plans determined by the Designated Official necessary to manage the Financial Conflict of Interest. The FCOI Designated Official of BIPS will submit the FCOI report to NIH via the eRA Commons FCOI module.

8. Monitoring Investigator compliance

BIPS will monitor Investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the Investigator disclosed the FCOI in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study concerned and send a copy of the communication to the Designated Official which will serve as documentation for compliance with the management plan.

9. Public accessibility of the FCOI policy and FCOI information held by Senior/Key Personnel

FCOI policy: A copy of the FCOI policy is posted on the Institution's public website per the NIH requirements in the NIH grants policy statement section 4.1.10 Financial Conflict of Interest at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm.

BIPS will ensure public accessibility of its policy by posting the FCOI policy on its publicly accessible website (www.bips-institut.de)

Identified FCOIs held by Senior/Key Personnel: Prior to the expenditure of any funds under an NIH award, BIPS will ensure public accessibility by providing a written response to any requestor **within five (5) business days** of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the Senior/Key Personnel as defined in Section 3;
2. BIPS has determined that the SFI is related to the Research funded through an award; and
3. BIPS has determined that the SFI is a Financial Conflict of Interest.

The information made available via the public website or in a written response will include at a minimum:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;

3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. The approximate dollar value of the Significant Financial Interest in the following ranges:
 USD 0 - USD 4,999; USD 5,000 - USD 9,999; USD 10,000 - USD 19,999; amounts between USD 20,000 - USD 100,000 by increments of USD 20,000; amounts above USD 100,000 by increments of USD 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.

The written response will note 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 FCOI which should be requested subsequently by the requestor.

If BIPS uses a publicly accessible website to meet this requirement, the information posted will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key Personnel related to the NIH-funded Research that was not previously disclosed, or
- A new SFI being disclosed by Senior/Key Personnel joining the project and determined by the designated official to be related to the research and an FCOI.

Information on SFIs subject to the public accessibility requirement will remain available for at least three years from the most recent update.

10. Reporting of identified Financial Conflicts of Interest

BIPS will assign an institutional official to serve as the FCOI Signing Official (SO) within the eRA Commons FCOI module. The FCOI SO has the authority to submit FCOI reports to the NIH. FCOI reports are submitted to the NIH only when a grant or cooperative agreement is active and an FCOI is identified (i.e., no award - no FCOI and no FCOI - no FCOI report). The FCOI module user guide is available at https://www.era.nih.gov/files/fcoi_user_guide.pdf to assist in submitting reports to the NIH.

Initial or original FCOI reports:

Prior to the expenditure of funds under a new award: When an FCOI is identified upon the issuance of a new NIH award, the FCOI SO will submit a NIH '2011 FCOI' original report prior to the expenditure of any funds under an NIH award. The original FCOI report will include the information required in the regulation at [42 CFR Part 50.605\(b\)\(3\)](#) or as outlined in NIH's FAQ H.5. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52888>

Within 60 days of identifying a new FCOI during award period: When an FCOI is identified during the period of an NIH-funded award (e.g., a new SFI is identified for an Investigator, or upon the participation of a new Investigator), BIPS will provide to NIH within 60 days of identifying the FCOI, an Original FCOI report regarding the Financial Conflict of Interest.

Annual FCOI reports: While the award is ongoing (including any extensions with or without funds), BIPS will provide NIH with an annual FCOI report that addresses the status of the previously reported FCOI (i.e., whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

- The annual FCOI report will be submitted at the same time as when the research performance progress report or multi-year progress report is due and at the time of grant extension, if applicable, per the NIH guidance (see NIH's FAQ H.2. at <https://grants.nih.gov/faqs#/financial->

[conflict-of-interest.htm?anchorff52860](https://www.fda.gov/oc/foi/conflict-of-interest.htm?anchorff52860)). The NIH will send an annual report email notification to the Institution when an annual report is due.

- Annual FCOI reports are not submitted as part of grant closeout.

Revision (or mitigation) FCOI reports: Following the completion of a retrospective review, the Institution will provide NIH with a revision if new information is discovered or a mitigation report if bias is found.

The types of FCOI reports and their requirements are summarized below:

Required FCOI reports to be provided to NIH through eRA Commons FCOI module		
Report	Content	Required when?
New FCOI report (Initial submission)	Grant Number, PI, name of entity with FCOI, nature of FCOI, value of Financial Interest (in increments), description of how FI relates to research, key elements of management plan.	1) Prior to expenditure of funds under a newly issued award; or 2) Within 60 days of any subsequently identified FCOI during the award.
Annual FCOI report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and changes to management plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is non-compliance with the regulation, if needed.
Mitigation Report	Project number, project title, contact PI/PD, name of Investigator with FCOI, name of entity with FCOI, reason for review, detail methodology, findings and conclusion.	When bias is found as a result of a retrospective review.

11. Training requirements

Each Investigator will be informed about BIPS' FCOI policy and trained on the Investigator's responsibility to disclose foreign and domestic SFIs per this policy and the FCOI regulation at [42 CFR part 50 subpart F](#). FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded Research, at least every four years, and immediately (as defined below) when any of the following circumstances apply:

1. BIPS revises this policy, or procedures related to this policy, in any manner that affects the requirements of Investigators;
2. An Investigator is new to BIPS research under an NIH award (training is to be completed prior to his/her participation in the Research); or
3. BIPS finds that an Investigator is not in compliance with this policy or a management plan issued under this policy (training is to be completed within 30 days in the manner specified by the Designated Official).

To ensure Investigators understand their responsibility to disclose SFIs per the policy, training will include the definition of 'institutional responsibilities' and Significant Financial Interests in addition to the information on when to disclose SFIs per Section 4.

To meet the training requirements of the FCOI regulation, the Institution will utilize either the NIH's financial conflict of interest tutorial or the "FCOI Presentation" located at

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html
<https://www.youtube.com/watch?v=D292YZ6BX24>, respectively.

and

The requirement to fulfill FCOI training is in accordance with the regulatory requirements and expectations of this policy.

The Institution will maintain documentation to ensure Investigator compliance with the training requirements. If the tutorial is used for training, the investigator will be required to provide a copy of the certificate to the Designated Official. If the FCOI presentation is used, the Investigator will be required to send an email to the Designated Official on the day the training was fulfilled.

12. Failure to comply with BIPS Financial Conflict of Interest policy applicable to Public Health Service funded award

Whenever the Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the Designated Official will within 60 days; review the SFI, determine whether the SFI is related to Research; determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward. The Institution will also submit an FCOI report to the PHS/NIH via the eRA Commons FCOI module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by BIPS to constitute a FCOI;
- Failure by BIPS to review or manage such a FCOI;
- Failure by the Investigator to comply with a management plan;

BIPS will, **within 120 days** of determining non-compliance:

Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any NIH-funded Research, or portion thereof, conducted during the period of the non-compliance was biased in the design, conduct, or reporting of Research;

Document the retrospective review consistent with the regulation at [42 CFR 50.605 \(a\)\(3\)\(ii\)\(B\)](#) or as described in NIH's FAQ I.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52895>

If bias is found, BIPS shall notify NIH promptly and submit a mitigation report per the regulation at [42 CFR 50.605\(a\)\(3\)\(iii\)](#) or as described in NIH's FAQ I.3. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52896> to NIH via the eRA Commons FCOI module that shall address:

- Impact of the bias on the research project, and
- BIPS' plan of action or actions taken to eliminate or mitigate the effect of the bias

Thereafter, BIPS will submit FCOI reports annually to NIH in accordance with the NIH guidance as provided in the summary chart above. Depending on the nature of the Financial Conflict of Interest, BIPS may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of BIPS' independent retrospective review.

If bias is not found, no further action will be taken unless new information is discovered that needs to be reported to the NIH. If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report

information (e.g., increase in value of the SFI or add any newly identified SFIs) following the completion of the retrospective review.

13. Clinical research requirements

If the department of health and human services 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 BIPS 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.

14. Subrecipient requirements

A subrecipient relationship is established when federal funds flow down from or through BIPS to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to BIPS for programmatic outcomes and compliance matters subrecipients, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to BIPS's terms and conditions. BIPS take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at [42 CFR part 50 subpart F](#).

BIPS will incorporate as part of a written agreement with the subrecipient, terms that establish BIPS FCOI policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s): See the NIH grants policy statement section 15.2.1 written agreement at https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm.

If the subrecipient's FCOI policy applies: The subrecipient institution will certify as part of the agreement with BIPS that its policy is in compliance with the federal FCOI regulation. The agreement shall specify the time period for the subrecipient to report all identified FCOIs to BIPS (e.g., within 55 days of identification to allow BIPS to report within 60 days) to enable BIPS to provide timely FCOI reports to the PHS/NIH as required by the regulation. BIPS assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA commons FCOI module.

If the subrecipient cannot provide certification: The agreement shall state that the subrecipient Investigator is subject to BIPS FCOI policy for disclosing SFI(s) that are directly related to the subrecipient's work for BIPS. BIPS will require the submission of all Investigator disclosures of SFIs to BIPS. The agreement will include sufficient time period(s) to enable BIPS to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, BIPS will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI module.

15. Maintenance of records

BIPS will keep all records of all Investigator disclosures of financial interests and BIPS' review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest), and all actions under this policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in [45 CFR. 75.361](#) for different situations. BIPS will retain records for each competitive segment as provided in the regulation.

Management plans will be retained as part of BIPS records.

In addition, the Institution will make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to such disclosure whether or not the disclosure resulted in the Institution's determination of an FCOI per the regulation [42 CFR 50.606\(b\)](#).

16. Enforcement actions when an Investigator fails to comply with this policy

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply with this policy are subject to a formal investigation by the BIPS compliance office to document the process and to determine appropriate corrective measures and disciplinary actions. Disciplinary actions can include letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.

17. Point of contact

For questions related BIPS's Financial Conflict of Interest policy or to disclose an SFI or potential FCOI, contact: verwaltungsleitung@leibniz-bips.de