

Policy on Financial Conflicts of Interest (FCOI)

(effective date: 14.2.2024)

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I. Preamble

The following policy on financial conflict of interest is applicable in relation to funding, by means of a grant or cooperative agreement, applied for or received from United States of America public sources, notably the Public Health Service (PHS) and others, as well as from those non-profit US foundations which require all awardee researchers to comply with the requirements of the US federal regulations on Financial Conflict of Interest (FCOI). The Institution and all Investigators (as defined in II. below) at Heidelberg University (UHEI) are required to comply with these regulations (also referred to as FCOI policy).

Besides this UHEI's FCOI policy, all funding activity at the UHEI related to US public health sources must comply with the grant policy guidelines of the respective funding awarding component (as e.g. *NIH Grant Policy Statement* and the *NSF Proposal and Award Policies and Procedures Guide*) and with all existing institutional and legislative policies, laws and regulations dealing with conflict of interest.

The requirements of the UHEI's policy are based on the 2011 revised FCOI regulation of the US 42 Code of Federal Regulation (CFR) Part 50, Subpart F and 45 CFR Part 94, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" and "NSF Proposal and Award Policies and Procedures Guide, Chapter IX, A".

UHEI and its Investigators may either function as a coordinator of a US-funded project (UHEI as *main awardee*) or as a partner in a project coordinated by a different university (UHEI as *subawardee*).

II. Purpose

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator. In the following, this policy defines the term Financial Conflict of Interest, describes responsibilities and the administrative procedure at UHEI to identify and manage FCOI cases.

III. Definitions

Department of Health and Human Services (HHS):

HHS means the US Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Disclosure of SFIs:

Refers to the Investigator's disclosure of Significant Financial Interests (SFIs) to UHEI.

FCOI report:

Means the UHEI's report of an FCOI to a PHS Awarding Component.

Financial Conflict of Interest (FCOI):

An FCOI exists when the designated official, see below, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest (FI):

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

Institution:

In general, this refers to any public or private entity or organization (excluding an US Federal agency) that is applying for, or receives, PHS research funding.

In this policy it means Heidelberg University (UHEI).

Institutional Official(s):

All members of the administration of UHEI, most notably of the Compliance Officer, are designated as Institutional Officials. They can be supported by members of the research division and the rectorate. Together they i.a.: solicit and review SFI disclosures, establish a management plan to eliminate identified FCOIs, ensure appropriate reporting and documentation.

Institutional responsibilities:

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of UHEI, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator:

Investigator means the project director (PD) or principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or other US sources as named above (Preamble), or proposed for such funding, which may include, for example, collaborators, consultants and subgrantees. For disclosure purposes, investigators completing the disclosure survey also must disclose interests of immediate family members, including the Investigator's spouse and dependent children.

Manage:

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

UHEI:

Heidelberg University

Project Director/Principal Investigator (PD/PI):

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

Public Health Service (PHS):

PHS means the Public Health Service of the US 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).

In this policy, the term PHS is used in relation to funding received from all US public sources and non-profit US foundations (see above I. Preamble).

Senior/key Personnel:

Means the PD/PI and any other person identified as senior/key personnel by UHEI in the grant application, progress report, or any other report submitted to the PHS by UHEI.

Significant Financial Interest (SFI):

An SFI means:

1. A financial interest consisting of one or more of the following interests of the Investigator and those of the Investigator's spouse and dependent children that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a) With regard to any publicly traded entity, an SFI 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;
 - b) With regard to any non-publicly traded entity, an SFI 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
 - c) 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 his/ her spouse or dependent children

not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. The disclosure is only required when the aggregate value in the last 12 months provided by any single entity exceeds US \$5,000. Moreover, this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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. This disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this FCOI policy, the Institutional Officials 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 SFI **does not include** the following types of financial interests: salary, royalties, or other remuneration paid by UHEI to the Investigator if the Investigator is currently employed or otherwise appointed by UHEI, including intellectual property rights assigned to UHEI and agreements to share in royalties related to such rights; 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; 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.

PHS Awarding Component:

This means the organizational unit of the PHS that funds the research that is subject to the FCOI regulation (e.g. the National Institutes of Health).

IV. Responsibilities

1) Responsibilities of Investigators

Investigators (see definition under III.) are responsible for the following:

- Complying with the UHEI's FCOI policy and procedures;
- Undertaking and passing FCOI trainings as described below (VI. Training Requirements)
- Disclosing SFIs and other required information to UHEI in a timely manner (see below "VII. SFI disclosure");
- Complying with management and corrective actions

2) Responsibilities of UHEI:

- Comply with the FCOI regulation, including developing, maintaining and communicating a written and enforced FCOI policy (including publicizing on UHEI's Web site);

- Informing Investigators of the FCOI policy, promoting and enforcing the Investigator's compliance to it, e.g. by directly contacting Investigators, by releasing notes on the Web site/Intranet, by offering trainings;
- Documentation of Investigator's FCOI training certificates and other verifications;
- Manage the SFI disclosure procedure: collecting and reviewing of all Investigators' SFI disclosures, determining which SFI is related to PHS-funded research and, if so, whether the SFI is an FCOI
- Developing and implementing of a management plan to reduce or eliminate an FCOI prior to expenditure of funds;
- Reporting FCOIs to the PHS awarding component or other US foundations (prior to the expenditure of funds and within 60 days of any subsequently identified FCOI); providing SFI-related information to the HHS upon request, whether or not the disclosure resulted in the Institution's determination of an FCOI
- Designating Institutional Officials to solicit and review disclosures of SFIs
- Maintaining records relating to all Investigator disclosures of SFIs and the Institution's response to such disclosures (whether or not a disclosure resulted in the Institution's determination of an FCOI) for at least three years from the date the final expenditures report is submitted to the PHS
- If UHEI is main awardee, manage FCOI regulation compliance regarding the respective subawardees

V. Enforcement Mechanisms / Noncompliance

1. Whenever the Institution identifies an SFI that was not disclosed timely by the Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the SFI; determine whether it is related to PHS-funded research; determine whether a 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;
- 2.a In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI; failure by the Institution to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- 2.b The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
 - Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has a FCOI;

- 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);
 - Findings of the review; and
 - Conclusions of the review.
3. Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in 42 CFR Part 50 Subpart F. Depending on the nature of the FCOI, the Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.
4. In addition, the non-compliance of an Investigator with this policy may result in one or more of the following administrative actions:
- The Institutional Officials will report the failure to comply with the FCOI regulation to the rectorate.
 - The Investigator will be deemed ineligible to maintain principal investigator status on US-sponsored projects
 - The individual will be deemed ineligible to enter into technology transfer agreements
 - The rectorate shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to suspending expenditures on a research account or institution disciplinary measures

VI. Training Requirements

Each Investigator (including subrecipient Investigators, if applicable) is required to complete training in relation to FCOI-related requirements described under this policy. This is due

- Prior to engaging in research related to any PHS-funded grant
- At least every four years
- Immediately, if
 - o UHEI revises this policy and this affects requirements of Investigators
 - o an Investigator is new to the UHEI
 - o An Investigator is not in compliance with the UHEI FCOI policy or management plan

Training consists of carefully reading and comprehending the UHEI's FCOI policy, and of undertaking the NIH Online FCOI Tutorial (see link below). In the event of uncertainty, the Institutional Officials provide further information upon request. In order to affirm the training requirements, the Investigator has to confirm in written form about the notice and willingness to adhere to the UHEI FCOI

policy. In addition, the Investigator must provide the Institutional Officials with the “Certificate of Completion” which is received upon successful participation in the online NIH tutorial.

VII. SFI Disclosure

Each Investigator must disclose SFIs (and those of the Investigator’s spouse and dependent children) to the Institutional Officials

- No later than at the time of application for PHS-funded research
- At least annually during the period of the award (e.g. at time of extension of a subcontract amendment)
- Within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance)

To this, the Investigator must complete and submit the “Disclosure Form on Financial Conflict of Interest (FCOI)” to the Institutional Officials of UHEI.

VIII. SFI Review and FCOI Identification

1. The Institutional Officials review all disclosure forms and determine whether any SFI relates to PHS-funded research and whether an FCOI exists.

An Investigator’s SFI is related to PHS-funded research when UHEI, through its designated officials, reasonably determines that the SFI could affect the PHS-funded research or is in an entity whose financial interest could be affected by the research.

The Institutional Officials are in charge of reviewing SFI disclosures. Further advice and guidance can be given by members of the Division Research.

2. An FCOI exists when UHEI, through its Institutional officials (see above) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

The Investigator may be involved in the Institutional Official’s determination of whether an SFI is related to the PHS-funded research.

- SFI disclosure reports are confidential. However, they can be disclosed to the above-named members of UHEI if necessary for clarification. Upon request, SFI disclosures must be reported to the PHS awarding component (e.g. NIH Chief Grants Management Officer) whether or not the disclosure resulted in the Institution’s determination of an FCOI.
- Investigators will be informed about the determination and consequences of the SFI disclosure.

3. In case UHEI functions as main awardee, UHEI must take reasonable steps to ensure that subawardee Investigators comply with this UHEI regulation.

IX. Management Plan

1. Prior to the expenditure of any funds under a PHS-funded research project, the Institutional Officials of UHEI shall review all Investigator disclosures and determine whether an SFI or FCOI exists, and if so, develop and implement a management plan that specify the actions that have been, and shall be, taken to manage such FCOI.

2. Management of an FCOI might implement imposing one or several of the following conditions, besides other provisions not listed here:

- Reduction or elimination of the Financial Interest (e.g., sale of an equity interest)
- Severance of relationships that create the FCOI

- 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
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from FCOIs
 - Disclosure of FCOI directly to human subjects research participants
 - Public disclosure of FCOIs (e.g., when presenting or publishing the research)
3. Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the project discloses an SFI or an existing Investigator discloses a new SFI, the Institutional Officials shall, within 60 days, perform the SFI review process (see above) and implement, on at least an interim basis, a management plan. The same procedure applies to the situation whenever UHEI identifies an SFI that was not disclosed timely by an Investigator or was not previously reviewed by UHEI in a timely manner.
 4. Whenever an FCO is **not** identified or managed **in a timely manner** (failure of disclosure, failure in reviewing, failure in complying with a management plan), UHEI shall, within 120 days of UHEI's determination of noncompliance complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. UHEI is required to document the retrospective review including key elements (as detailed in § 50.605 of 42 CFR Part 50).
Subsequently, if appropriate, UHEI shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI. If bias is found, UHEI is required to notify the PHS awarding component promptly and submit a mitigation report (as detailed in § 50.605 of 42 CFR Part 50).
 5. Whenever UHEI implements a management plan, UHEI shall monitor the Investigator compliance with this plan on an ongoing basis until the completion of the research project.
 6. Furthermore, management of FCOI requires that, prior to the expenditure of any funds under a PHS-funded research project by UHEI, information concerning any SFI disclosed to UHEI is made available via written response to any requestor within five business days of a request under the following conditions:
 - The SFI was disclosed and is still held by the senior/key personnel;
 - UHEI determines that the SFI is related to the PHS-funded research,
 - And UHEI determines that the SFI is an FCOI.

The information that UHEI makes available shall include and remain available for three years from the date the information was most recently updated:

- The Investigator's name;
- the Investigator's title and role with respect to the research project;
- the name of the entity in which the SFI is held;
- the nature of the SFI;
- the approximate dollar value of the SFI (as described below under X.)
- the note that the information provided is current as of the date of the correspondence and is subject to updates, on an annual basis and within 60 days of the identification by UHEI of a new FCOI, which should be requested subsequently by the requestor.

X. Reporting of FCOIs

1. Prior to the expenditure of funds under a PHS-funded research project or within 60 days of any subsequently identified FCOI, UHEI shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by UHEI to be conflicting and ensure that UHEI has implemented a management plan in accordance with the FCOI regulation. In cases in which an FCOI is eliminated prior to the expenditure of PHS-awarded funds, the reporting to the PHS Awarding Component is not necessary.

The FCOI report shall include the following information:

- Project number;
 - PD/PI or Contact PD/PI if a multiple PD/PI mode model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Nature of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - Value of the financial interest (dollar ranges are permissible: 0-\$4,999; \$5,000-\$9,999; \$10,000- \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - A description of how the financial interest relates to the PHS-funded research and the basis for UHEI's determination that the financial interest conflicts with such research; and
 - A description of the key elements of the management plan of UHEI, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.
2. For any FCOI previously reported by the UHEI with regard to an ongoing PHS-funded research project, UHEI shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the managing plan for the duration of the PHS-funded research project. The annual report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.
In cases of retrospective review, UHEI is required to notify the PHS Awarding Component promptly and submit a mitigation report, if bias was found (see also above IX.4).

XI. Remedies

1. In case of non-compliance of Investigators with this policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, UHEI shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to UHEI for further action.

2. The PHS Awarding Component and /or HHS may inquire at any time before, during, or after award into any Investigator disclosure of Financial Interests and the UHEI's review of, and response to, such disclosure, regardless of whether the disclosure resulted in UHEI's determination of an FCOI. UHEI is required to submit, or permit on-site review of, all records pertinent to compliance with the FCOI regulation. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that UHEI has not managed the FCOI in accordance with the FCOI regulation. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.
3. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by UHEI as required by the FCOI regulation, UHEI shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. Subrecipient Requirements

In case UHEI functions as main awardee and carries out the PHS-funded research through a subrecipient, UHEI must take reasonable steps to ensure that any subrecipient Investigator complies with the FCOI regulation (based on *US 42 Code of Federal Regulation (CFR) Part 50, Subpart F*).

- Incorporating as part of a written agreement (see "Subrecipient FCOI Certification Form") with the subrecipient terms that establish whether the FCOI policy of UHEI or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement that its policy complies with the applicable PHS requirements. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI regulation of UHEI for disclosing SFIs that are directly related to subrecipient's work for the UHEI.
- All identified FCOIs must be reported within 30 days of receiving notice of the conflict by the subrecipient to UHEI.
- If the subrecipient's Investigator must comply with UHEI's FCOI policy, the subrecipient must submit all SFI disclosures to UHEI within 30 days of receiving notice of the SFI. UHEI reviews these disclosures as described above (**VII, VIII**).
- UHEI has to provide FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators under conditions as described above (i.e., prior to the expenditure of funds and within 60 days of subsequently identified FCOI).

Entry into Force

These regulations enter into force as of February 14th 2024.

Attachments:

- Disclosure Form
- Subrecipient Financial Conflict of Interest Certification

Abbreviations:

CFR: Code of Federal Regulations (of the United States of America)

FCOI: Financial Conflict of Interest

HHS: US Department of Health and Human Services

UHEI: Ruprecht-Karls-Universitaet Heidelberg (Heidelberg University)

PD: Project Director

PHS: Public Health Service (of the United States of America)

PI: Principal Investigator

SFI: Significant Financial Interest

US: United States of America

Links:

NIH FCOI regulations:

<https://grants.nih.gov/grants/policy/coi/index.htm>

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>

FCOI training (NIH):

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

42 CFR 50 Subpart F:

https://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

NIH Grant Policy Statement:

<https://grants.nih.gov/policy/nihgps/index.htm>

NSF Grant Policy Manual:

<https://coi.mit.edu/sponsor-specific-guidelines/national-science-foundation-nsf>

https://www.nsf.gov/pubs/policydocs/pappg20_1/nsf20_1.pdf