

Beslut om Riktlinjer för hantering av ekonomiska intressekonflikter vid forskning som finansieras av amerikanska bidragsgivare

Beslut

Linköpings universitet (LiU) beslutar att ”Riktlinjer för hantering av ekonomiska intressekonflikter vid forskning som finansieras av amerikanska bidragsgivare” ska träda i kraft i enlighet med de ikraftträdandebestämmelser som anges i styrdokumentet (se bilaga).

Styrdokumentet ska föras in i regelsamlingen och ersätter tidigare beslut om Policy och riktlinjer angående ansökningar/beviljade medel från federala amerikanska finansierare från den 28 oktober 2013 (dnr LiU-2013-01757).

Skäl till beslut

Forskningsfinansiering från federala myndigheter i USA omfattas av ett stort regelverk. Flertalet stiftelser och andra privata finansierare i USA hänvisar också helt eller delvis till det federala regelverket i bidragsvillkor, policyer etc. Privata finansierare har även i varierande omfattning egna regelverk.

Exempelvis bidragsfinansiering från organisationer under Public Health Service, bland andra National Institutes of Health, Centers for Disease Control and Prevention, U.S. Food and Drug Administration kräver att organisationer som beviljas medel från dem har en policy för hantering av finansiella intressekonflikter. LiU har sedan 2013 en sådan policy och riktlinjer som nu ersätts med uppdaterade riktlinjer.

Syftet med riktlinjerna är att säkerställa redovisning och hantering av ekonomiska intressekonflikter vid forskning med medel från amerikanska finansierare. Riktlinjerna ska tillämpas på all forskning från amerikanska finansierare som kan omfattas av riktlinjerna.

Riktlinjerna upprättas på engelska och svenska. Den svenska versionen kommer att göras tillgänglig efter den engelska versionen. Vid eventuella språkliga skillnader ska vägledning för tolkningen inhämtas från den bakomliggande lagstiftningen 42

Code of Federal Regulations Part 50 Subpart F, Promoting Objectivity in Research.

Handläggningen av beslutet

Beslut i detta ärende har fattats av prorektor Karin Axelsson vid rektors beslutsmöte i närvaro av den tillförordnade universitetsdirektören Per-Olof Brehmer, chefsjuristen Christina Helmér, studentrepresentanten Anna Wikström, juristen Brian Price och sekreteraren Jenny Ewen Waldén, efter föredragning av biträdande chefsjuristen Kristina Sundström.

I ärendets beredning har juristen Brian Price deltagit. Redaktionen för regelsamlingen har granskat beslutets form.

Karin Axelsson

Kristina Sundström

Sändlista:

Universitetsledningen
Universitetsdirektörens ledningsgrupp
Dekanerna (funktionsadresser)
Prefekterna
Institutionerna (de administrativa cheferna)
Överbibliotekarien
Internrevisionen
Berörda lokala fackliga organisationer
Innehållsredaktionen
Studentkårerna
Regelsamlingen
Dokument- och arkivenheten (original)

Guidelines for handling of financial conflicts of interest for research with U.S. funded grants

1 Introduction

1.1 Background

In order to accept funding from entities that are a part of the United State Public Health Service (PHS) such as the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and others, LiU is required to have in place a policy that addresses and regulates Researchers' financial conflicts of interest (FCOI). These guidelines must be consistent with U.S. regulations and must be publicly available. LiU has therefore produced these guidelines for handling of FCOI for research with U.S. funded grants. LiU has decided that, although the regulations are specific to the PHS, it shall apply parts of these guidelines to all research funding that originates from the United States.

1.2 Purpose and Scope

These guidelines are derived from 42 Code of Federal Regulations (CFR) Part 50 Subpart F, Promoting Objectivity in Research. The original purpose of the regulations was 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 or subcontracts will be free from bias resulting from Researcher FCOI. This included funding from entities such as the NIH, CDC, FDA, and others. As part of its guidelines pursuant to these regulations, LiU has determined that it should largely apply to all research funding originating from the United States, including that from U.S. private foundations which have adopted the PHS rules. As such, these guidelines are applicable to any Researcher who is planning to participate in, or is participating in, U.S. funded research by means of a grant, cooperative agreement, or subcontract.

2 Brief Description

These guidelines have two main parts: the steps that Researchers participating in U.S. funded research must take; and the steps that LiU must take in response to relevant information disclosed to it by its Researchers. These will be described in turn.

First, LiU must notify its Researchers of these guidelines, the Researchers' responsibilities regarding disclosure of significant financial interests, the NIH's regulations themselves (42 CFR Part 50 Subpart F), and the training required for all Researchers seeking or taking part in U.S. funded research. Although defined in more detail below, a Researcher has a significant financial interest when the Researcher, the Researcher's spouse, domestic partner, or dependent children have one or more of the following financial interests that reasonably appears to be related to the Researcher's institutional responsibilities:

- Financial interest with regard to any publicly traded entity, remuneration from and any equity interest in that entity which, when aggregated, exceed \$5,000.
- Financial interest with regard to any non-publicly traded entity, remuneration in excess of \$5,000 **or** any equity interest.
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Any reimbursed or sponsored travel related to their institutional responsibilities (except for that travel reimbursed or sponsored by certain government, higher education, or medical or research entities).

Next, under these guidelines, LiU must

- designate an institutional official who shall review disclosures of significant financial interests,
- provide guidelines for that official to evaluate any significant financial interests or FCOI,
- manage and report on any FCOI,
- maintain records of disclosures of financial interests and LiU's processes related thereto, and
- establish ways to enforce or ensure Researcher compliance with these guidelines.

LiU also must certify that these requirements will be followed when applying for relevant PHS funding.

3 Definitions

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of U.S. funded research.

FCOI report means an Institution's report of a FCOI a PHS Awarding Component.

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

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

Institutional responsibilities means a Researcher 's professional responsibilities on behalf of LiU, which include, but are not necessarily limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage means taking action to address a 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.

PD/PI means a project director or principal investigator of a U.S. funded research project; the PD/PI is included in the definitions of senior/key personnel and Researcher under these guidelines.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

PHS Awarding Component means the organizational unit of the PHS that funds research that is subject to these guidelines.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). It also includes any such activity for which research funding is available from a PHS Awarding Component or similar through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Researcher 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 U.S. funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by LiU in the grant application, progress report, or any other report submitted to a U.S. funding entity.

Significant financial interest means a financial interest consisting of **one or more of the following interests** of the Researcher (and those of the Researcher's spouse, domestic partner, and dependent children) that reasonably appears to be related to the Researcher's institutional responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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.
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Researcher (or the Researcher's spouse, domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Researchers also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Researcher and not reimbursed to the Researcher so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. LiU's designated official (särskilt utsedd tjänsteman) 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 U.S. funded research.

The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by LiU to the Researcher if the Researcher is currently employed or otherwise appointed by LiU, including intellectual property rights assigned to LiU 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 Researcher does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

U.S. funded research includes, but is not limited to, funding from United States based entities such as the PHS, Department of Energy (DOE), National Science Foundation (NSF), National Aeronautics and Space Administration (NASA), and others, and also includes United States based private foundations and non-governmental organizations which have adopted similar requirements.

4 Researcher Obligations

Pursuant to these guidelines, Researchers must

- complete training regarding significant financial interests and conflicts (described below in Section 5),
- disclose significant financial interests (as further described below in Section 6), and
- be aware of these guidelines and the federal regulations underlying it, 42 CFR Part 50 Subpart F, available at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>, as may be updated from time to time.

5 Researcher Training

All Researchers are required to complete training regarding significant financial interests and conflicts. There are three main events which trigger this training requirement:

- First, all Researchers must complete training regarding significant financial interests and conflicts of interest **prior to engaging in research related to any U.S. funded grant.**
- Following that initial training, Researchers must refresh their training regarding significant financial interests and conflicts **at least every four years when engaged in research related to PHS-funded grants.**
- Finally, Researchers must **immediately** complete training regarding significant financial interests and conflicts when
 1. LiU revises these guidelines in any manner that affects the requirements of Researchers,

2. a Researcher is new to LiU, or
3. LiU finds that a Researcher is not in compliance with these guidelines or FCOI management plan.

All Researchers must provide the Grants Office with notification of every completed training.

6 Researcher Disclosure of Significant Financial Interests

As part of the requirement of disclosure of significant financial interests, any Researcher who is participating in U.S. funded research must complete LiU's Significant Financial Interest Disclosure Form. This is required whether or not a Researcher has a significant financial interest. As part of this requirement a Researcher must meet the following requirements:

- Disclose to LiU's designated official the Researcher's significant financial interests (and those of the Researcher's spouse, domestic partner and dependent children) no later than the time of application for PHS-funded research.
- Submit an updated disclosure of significant financial interests on December 1 of each year during the period of the award. Such disclosure shall include any information that was not disclosed initially to LiU pursuant to the preceding paragraph, or in a subsequent disclosure of significant financial interests (e.g., any FCOI identified on a U.S. funded project that was transferred from another organization), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- Submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Researchers must submit the form at least one month before filing an application for funding or entering into a subcontract to enable LiU to timely complete its review, management, and reporting obligations, and such that LiU can provide FCOI reports to the PHS Awarding Component regarding all FCOI interest of all subrecipient Researchers consistent with this subpart (prior to the expenditure of funds **and** within 60 days of any subsequently identified FCOI).

The department shall send the Significant Financial Interest Disclosure Form to the Grants Office (gpo@liu.se). Any disclosure of significant financial interests shall include either an explanatory statement or an overview from the head of the department. The statement shall be recorded at the department. The Grants Office shall, if necessary, within one week request clarification for further information from the Researcher's department. If requested, the department shall within one week provide the Grants Office with the additional information.

If a Researcher fails to comply with any of the disclosure requirements of this section, the Grants Office shall notify the head of the Researcher's department, who

will prohibit access to the granted funding or prohibit the Researcher's application to the PHS. The department head may also

- restrict any Researcher applications for new funding (foreign or otherwise), until the Researcher has complied and the situation has been resolved, and
- take any other necessary actions as determined by the head of the department.

The Researcher's department shall register (diarieföra) these actions and notify the Grants Office of any steps taken.

7 LiU's Designated Official

LiU's designated official is designated and authorized in LiU's delegation of authority (Rektors delegation av beslutanderätten i allmänna förvaltningsärenden m.m.). The designated official is assigned to solicit and review disclosures of significant financial interests from each Researcher who is planning to participate in, or is participating in, U.S. funded research. The designated official will be assisted in solicitation and review by the Grants Office and the head of the Researcher's department (or relevant personnel in the event of a conflict), who will prepare the issue and provide a written recommendation to the designated official. The designated official may also seek assistance and advice from others, such the Grants Office or Legal Office, as necessary.

8 When is a Significant Financial Interest a FCOI?

A Researcher's significant financial interest is related to U.S. funded research when LiU, through its designated official, reasonably determines that the significant financial interest

- could be affected by the U.S. funded research, or
- is in an entity whose financial interest could be affected by the research.

LiU may involve the Researcher in the designated official's determination of whether a significant financial interest is related to the U.S. funded research.

A FCOI exists when LiU, through its designated official, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the U.S. funded research.

9 Management of FCOI

LiU shall take such actions as necessary to manage FCOI. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report. The Researcher's department shall register (diarieföra) the decided management of a FCOI and notify the Grants Office.

The following sections apply specifically to PHS funded Research and Research sponsored by other entities which have adopted the PHS FCOI regulations,

although LiU reserves the right to apply them or use them as guidance in handling any other U.S. funded research FCOI issues.

1. Prior to LiU's expenditure of any funds under a PHS-funded Research project, the designated official shall: review all Researcher disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded Research; determine whether a FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI. In managing a FCOI LiU may take any or all of the following steps (please note that this is not intended to be an exclusive list):
 - a. Public disclosure of the FCOI (e.g., when presenting or publishing the Research).
 - b. For Research projects involving human subjects Research, disclosure of the FCOI directly to participants.
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI.
 - d. Modification of the Research plan.
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research.
 - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
 - g. Severance of relationships that create financial conflicts.
2. Whenever, in the course of an ongoing PHS-funded Research project, a Researcher who is new to participating in the Research project discloses a significant financial interest or an existing Researcher discloses a new significant financial interest to LiU, the designated official shall, within sixty days: review the disclosure of the significant financial interest; 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. Depending on the nature of the significant financial interest, LiU may determine that additional interim measures are necessary with regard to the Researcher's participation in the PHS-funded Research project between the date of disclosure and the completion of LiU's review.
3. Whenever LiU identifies a significant financial interest that was not disclosed timely by a Researcher or, for whatever reason, was not previously reviewed by the LiU during an ongoing PHS-funded Research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded Research; determine whether a FCOI exists; and, if so take the following actions:
 - a. 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.
 - b.
 - i. In addition, whenever a FCOI is not identified or managed in a timely manner, including failure by the Researcher to

- disclose a significant financial interest that is determined by LiU to constitute a FCOI; failure by LiU to review or manage such a FCOI; or failure by the Researcher to comply with a FCOI management plan, LiU shall, within 120 days of LiU's determination of noncompliance, complete a retrospective review of the Researcher'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.
- ii. LiU is required to document the retrospective review. Such documentation shall include, but not necessarily be limited to, all of the following key elements:
 1. Project number.
 2. Project title.
 3. PD/PI or contact PD/PI if a multiple PD/PI model is used.
 4. Name of the Researcher with the FCOI.
 5. Name of the entity with which the Researcher has a FCOI.
 6. Reason(s) for the retrospective review.
 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
 8. Findings of the review.
 9. Conclusions of the review.
 - c. Based on the results of the retrospective review, if appropriate, LiU shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, LiU 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 LiU'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, LiU will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the FCOI, LiU may determine that additional interim measures are necessary with regard to the Researcher's participation in the PHS-funded Research project between the date that the FCOI or the Researcher's noncompliance is determined and the completion of LiU's retrospective review.
4. Whenever LiU implements a management plan pursuant to this subpart, LiU shall monitor Researcher compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
 5.
 - a. Prior to LiU's expenditure of any funds under a PHS-funded Research project, LiU shall ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to LiU that meets the following three criteria:

- i. the significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart,
 - ii. LiU determines that the significant financial interest is related to the PHS-funded research, and
 - iii. LiU determines that the significant financial interest is a FCOI.
 - b. The information that LiU makes available via written response to any requestor within five business days of a request shall include, at a minimum, the following: the Researcher's name; the Researcher's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, 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.
 - c. LiU's response to written requests pursuant to this subsection 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 LiU's identification of a new FCOI, which should be requested subsequently by the requestor.
 - d. Information concerning the significant financial interests of an individual subject to paragraph 5 of this section shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

10 Reporting of FCOI

This section only applies to PHS-funded Research.

1. Prior to LiU's expenditure of any funds under a PHS-funded Research project, LiU shall provide to the PHS Awarding Component a FCOI report regarding any Researcher's significant financial interest found by LiU to be conflicting and ensure that LiU has implemented a management plan in accordance with this subpart. In cases in which LiU identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, LiU shall not submit a FCOI report to the PHS Awarding Component.
2. For any significant financial interest that LiU identifies as conflicting subsequent to the LiU's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of a Researcher who is new to the research project), LiU shall provide to the PHS Awarding Component, within sixty days, a FCOI report regarding the FCOI and ensure that LiU has implemented a management plan in accordance with this subpart. Pursuant to paragraph 3 b of Section 9, where such FCOI report involves a significant financial interest that was not disclosed timely by a Researcher or, for whatever reason, was not previously reviewed or managed by LiU (e.g., was not timely reviewed or reported by a subrecipient), LiU also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. Additionally, pursuant to Section 9 3 c, if bias is found, LiU is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
3. Any FCOI report required under the two preceding subsections of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict,

and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:

- a. Project number.
 - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used.
 - c. Name of the Researcher with the FCOI.
 - d. Name of the entity with which the Researcher has a FCOI.
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
 - f. Value of the financial interest (dollar ranges as described in the regulation are permissible), 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.
 - g. A description of how the financial interest relates to the PHS-funded Research and the basis for the LiU's determination that the financial interest conflicts with such Research.
 - h. A description of the key elements of LiU's management plan, including the following:
 - i. Role and principal duties of the conflicted Researcher in the research project.
 - ii. Conditions of the management plan.
 - iii. How the management plan is designed to safeguard objectivity in the Research project.
 - iv. Confirmation of the Researcher's agreement to the management plan.
 - v. How the management plan will be monitored to ensure Researcher compliance
 - vi. Other information as needed.
4. For any financial conflict of interest previously reported by LiU with regard to an ongoing PHS-funded research project, LiU shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. LiU shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

11 Maintenance of Records

LiU shall maintain records relating to all Researcher disclosures of financial interests and LiU's review of, and response to, such disclosures (whether or not a disclosure resulted LiU's determination of a FCOI) and all actions under these guidelines or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations. LiU shall make information available, promptly upon request, to the HHS relating to any Researcher disclosure of financial interests and LiU's review of, and response to, such disclosure, whether or not the disclosure resulted in the LiU's determination of a FCOI.

12 Remedies

This section is only applicable to PHS funded Research and to entities which have adopted the PHS's regulations on FCOI. The following points outline the steps that LiU, the PHS Awarding Component, or HHS may take to review and address compliance with these guidelines.

1. If the failure of a Researcher to comply with these guidelines or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, LiU 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 LiU for further action, which may include directions to LiU on how to maintain appropriate objectivity in the PHS-funded Research project. PHS may, for example, require LiU to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such a Researcher.
2. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Researcher disclosure of financial interests and LiU's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in LiU's determination of a FCOI. LiU must submit, or permit on site review of, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that LiU has not managed the FCOI in accordance with this subpart. The PHS Awarding Component may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, 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 a Researcher with a FCOI that was not managed or reported by LiU as required by this subpart, LiU shall require the Researcher involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

13 Subcontracting

To the extent that LiU carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), LiU as awardee Institution shall take reasonable steps to ensure that any subrecipient Researcher complies with this subpart by:

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether these guidelines or the subrecipient's FCOI policy applies to the subrecipient's Researchers.
 - a. If the subrecipient's Researchers must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this

subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Researchers are subject to these guidelines for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution.

- b. Additionally, if the subrecipient's Researchers must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to LiU. Such time period(s) shall be sufficient to enable LiU to provide timely FCOI reports, as necessary, to the PHS as required by this subpart.
 - c. Alternatively, if the subrecipient's Researchers must comply with these guidelines, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Researcher disclosures of significant financial interests to LiU. Such time period(s) shall be sufficient to enable LiU to comply timely with its review, management, and reporting obligations under this subpart.
2. Providing FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Researchers consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

14 Entry into force

These guidelines will enter into force on the 1st of January 2024.

Signature page

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