



LUNDS
UNIVERSITET

Vice-Chancellor

DECISION (translation)

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18 May 2017

Reg. no STYR 2017/752

University Policy on Financial Conflict of Interest regarding Research Funding from some American Federal Funding Agencies

Background

In connection with applications for research funding, and in order to receive research funding from US governmental agencies, particularly the National Institutes of Health (NIH) but also some private funding agencies, Lund University and its researchers must comply with US legislation. Among other things, the University is responsible for identifying and managing any financial conflicts of interest of its researchers, in accordance with the 42 Code of Federal Regulation, Part 50, Subpart F, "Promoting Objectivity in Research", which regulates how any financial conflicts of interest (FCOI) are to be reported and managed. The US government wants to ensure that research funded with US government funds adheres to good research practice and is free from bias related to financial interests.

The regulations in the appendix have been drawn up in accordance with US regulations and adapted to Swedish legislation. The regulations are complementary to the University's current rules on conflicts of interest and secondary employment.

Decision

The University hereby adopts the Policy on financial conflicts of interest related to research funded by the United States. The policy takes effect on 18 May 2017.

The decision on this matter was taken by the undersigned vice-chancellor, in the presence of university director Susanne Kristensson, following a briefing by a representative of the Lund University Student Unions (LUS) and a presentation by head of office Anneli Wiklander. Legal counsel Sara Lindgren, at the Legal Services Office, also participated in the processing of the matter.

Torbjörn von Schantz

Anneli Wiklander
(Research, External Engagement and
Innovation – Research Services)

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LU Rules and Regulations



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University Policy on Financial Conflict of Interest regarding Research Funding from some American Federal Funding Agencies

This policy was adopted by the Vice-Chancellor on 18 May 2017.

Under the Higher Education Act article 2 section 5, Lund University provides as follows.

PURPOSE

Lund University adopts this Policy on Financial Conflict of Interest to promote objectivity in research funded by the Public Health Services (PHS) of the United States Department of Health and Human Services, which includes funding from the National Institutes of Health (NIH). The Policy intends to comply with PHS regulations of 42 CFR 50 Subpart F and 45 CFR 94. It establishes standards that provide a reasonable expectation that the design, conduct, and reporting of such PHS-funded research are free from bias resulting from Investigators' Financial Conflicts of Interest. The Policy applies to all PHS-sponsored Investigators of Lund University. The Policy can also be applied on research funded by other federal and private funding agencies of the United States, when applicable to their regulations.

DEFINITIONS

Equity means any interest in the profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

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

Significant Financial Interest means a Financial Interest, as listed below, 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) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any Equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an Equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of NIH-sponsored research.

FCOI Review Committee is a committee that is summoned to convene when a Significant Financial Interest (SFI) has been disclosed and further action is needed. The aim of the Committee is to assess the SFI and to propose measures to handle conflicts, e.g. a management plan may be set up. If an FCOI cannot be managed in what the FCOI Review Committee deems as an appropriate manner, the participation in a proposal or participation in a project may be canceled.

The Committee consists of the Dean of the Faculty and the Head of Department where the SFI has been disclosed, an in-house legal counsel from the university and a research adviser from the Research Services also participates. The final decision rests upon the Dean of the Faculty. The decisions of the Committee shall be made in writing and be archived at the department and at the Research Services.

Institution means the organization that is applying for, or that receives, PHS research funding.

Institutional Official (IO) means one or more persons designated by the Institution as having responsibility and authority for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's Institutional Responsibilities. The IO is assisted by a research adviser from the Research Services. The IO is also responsible for the compliance with any FCOI management plans at the department level.

For the purposes of this Policy, the Institutional Official is the Head of Department at the department that receives NIH funds on behalf of the Investigator.

Institutional Responsibilities means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research,

teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of NIH sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Management Plan means a written plan instituted by the University for the management, reduction or elimination of a Financial Conflict of Interest.

Policy means this Financial Conflict of Interest Policy.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Senior/Key Personnel means the Principal Investigator and any other person identified as senior or key personnel by the university in a grant application, award, or contract or in any progress report, or any other report submitted to the PHS or other funding source.

CONFLICT OF INTEREST

Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this Policy informs Investigators about situations that generate conflicts of interest related to Research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

The main responsibility for the full process of the disclosure of conflicts of interest rests with the Institutional Official. The Research Services assists the Institutional Official with the distribution, receipt, processing, review and retention of disclosure forms. The original documents should be archived at the concerned department and scanned copies provided to Research Services.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside Financial Interests (including

those of their spouse and dependent children) as defined above to the Institution on an annual and on an ad hoc basis, i.e. not:

- salary, royalties or other remuneration from the Institution, income from authorship of academic or scholarly works;
- income from the authorship of academic or scholarly works;
- income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for governmental agencies; institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these financial vehicles.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the Investigator's Institutional Responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official by the 1st of December annually.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into NIH-sponsored projects or applications for NIH-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

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

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value

if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's Research.

2) REVIEW AND DECISION MAKING PROCESS

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official and a research adviser from the Research Services for a determination of whether it may constitute a Financial Conflict of Interest.

If there is a potential Financial Conflict of Interest, the Research Services will summon the FCOI Review Committee to assess the disclosure.

A Financial Conflict of Interest will exist when the FCOI committee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of NIH-sponsored Research.

The Committee will propose appropriate actions, the Human Resources will be consulted when appropriate, and the dean of the faculty involved will make the final decision on how to manage the Financial Conflict of Interest. The action may include requirements of reduction or elimination of the conflict, as appropriate.

If the Financial Conflict of Interest can be managed, a written management plan must be developed and implemented. The affected Investigator must formally agree to the proposed management strategies and sign a written management plan before any related NIH-sponsored Research goes forward.

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

3) REPORTING TO NIH

The Institutional Official will in collaboration with Research Services report Financial Conflicts of Interest or non-compliance to NIH in accordance with NIH-regulations. If the funding for the Research is made available from a prime NIH-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest such that the prime awardee may fulfill their reporting obligations to the NIH. FCOI reports for NIH-funded Research contracts should be submitted to the NIH Contracting Officer identified on the contract.

4) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

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

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator. The Institution will promptly notify the NIH Awarding Component of the action taken or to be taken. If the funding for the Research is made available from a prime NIH awardee, such notification shall be made promptly to the prime awardee for reporting to NIH.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official will complete a retrospective review of the Investigator's activities and the NIH-sponsored research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the NIH or the prime NIH-awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in NIH regulations. If bias is found, the Institution will promptly notify the NIH Awarding Component and submit a mitigation report in accordance with the NIH regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5) TRAINING

Each Investigator must complete training on this Policy, the Investigator's Responsibilities regarding disclosure and the NIH regulations prior to engaging in Research funded by NIH, and at least every four years thereafter. The training will be arranged the Research Services in connection with the project meeting that is scheduled before the starting date of all NIH-funded research projects. The Investigators must also complete training within a reasonable period of time as determined by the Research Services in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the

Investigator is new to the Institution, or if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities.

6) SUBRECIPIENT MONITORING

In the case of subrecipients, the Institution will establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee institution or the FCOI policy of the recipient. The subrecipient will report any FCOIs to the awardee institution, and the awardee institution will forward the identified FCOIs to the funding agency.

7) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the NIH or to the prime NIH awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

8) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the NIH Awarding Component and to a requestor of information concerning Financial Conflicts of Interest related to NIH funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9) PUBLIC ACCESSIBILITY

The Institutional Official shall respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Senior and Key Personnel;
- b) A determination has been made that the Significant Financial Interest is related to the NIH-funded Research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the NIH regulation.