

# Instructions for managing financial conflicts of interest in research projects funded by US federal health agencies

Dnr 1-106/2024

Valid from 2024-04-02

NOTE: This is a translation of the Swedish version (*Anvisningar för hantering av ekonomiska intressekonflikter i forskningsprojekt finansierade av amerikanska federala hälsomyndigheter*). In the event of any discrepancy between the versions, the Swedish version constitutes the official decision, and the Swedish wording will prevail.



**Karolinska  
Institutet**



# Instructions for managing financial conflicts of interest in research projects funded by US federal health agencies

## Content

Introduction .....	4
These rules apply specifically to grants funded by PHS and should be followed in parallel with other reporting requirements for conflicts of interest at KI.....	5
Purpose.....	5
1. Scope .....	5
2. Definitions.....	6
3. The researcher's and KI's responsibilities.....	9
3.1 The researcher's responsibilities.....	9
• Declare any significant financial interests.....	9
• Provide updates to announced information as needed.....	9
• If acting as PI/PD, provide a list of individuals who meet the definition of "researcher" within the required announcement timeline.....	9
• Carry out the necessary training.....	9
• Complete the annual FCOI form, even if you have no financial interests to report.....	9
• Ensure that an updated FCOI form is available with the CDO before new research applications funded by PHS are submitted.....	9
3.2 KI's responsibilities .....	9
4. Order of handling .....	10
4.1 Members of the FCOI committee.....	10
4.2 Notification of significant financial interests.....	11

4.3 Significant Financial Interest Review Process.....	11
4.3.1 Review of new significant financial interests .....	12
4.3.2 Review of existing significant financial interests .....	12
4.3.3 Ex post review of significant financial interests .....	12
4.4 Management of financial conflicts of interest.....	13
4.5 Reporting requirements to NIH .....	13
4.5.1 FCOI report .....	13
4.5.2 Yearly FCOI report .....	13
4.5.3 Updating the FCOI report .....	13
4.6 Requirements for subrecipients.....	14
4.7 Education requirements .....	14
4.8 Documentation.....	15
4.9 Requirements for public accessibility.....	15

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Registration No. (Dnr)	Dnr prev. version:	Decision date:	Valid until:
Dnr 1-106/2024	Dnr 1-852/2020	2024-04-02	Further notice
Decision:		Document type:	
President		Instructions	
Handled by section/unit:		Preparation with:	
Research Support Office/Compliance & Data Office		Legal office	
Revised with respect to:	Committee members, changing from Grants Office to Compliance & Data Office and linguistic adjustments without change in substance.		

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## Introduction

National Institutes of Health (NIH) in the United States (US) provides research grants through the federal government agencies within U.S. Public Health Services (PHS).

PHS consists of various agencies including, but not limited to:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Office of Global Affairs (OGA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Office of the Assistant Secretary for Preparedness and Response (OASPR)
- Office of the Assistance Secretary for Health (OASH)

In cases where researchers at Karolinska Institutet (KI) receive grants from PHS, far-reaching demands are placed on researchers' objectivity and independence from commercial ties to companies that could influence the design, implementation and reporting of the research. Since KI is the grant recipient of PHS, the university has established instructions and processes in accordance with US federal regulations that require KI researchers (including the researcher's spouse/partner and/or minor children) to account for compensation and benefits paid from financial investments and ownership in companies.

These instructions correspond to US federal regulations set forth in “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contracts (Section of 42 CFR part 50 subpart F) to identify, manage and report financial conflicts of interest”.

These rules apply specifically to grants funded by PHS and should be followed in parallel with other reporting requirements for conflicts of interest at KI.

## **Purpose**

The purpose of these instructions is to ensure the objectivity of the research so that the design, implementation and reporting of funded research, grants or collaboration agreements shall be free from the influence of the researcher's financial conflicts of interest (including the researcher's spouse and/or minor children).

Of the relevant US federal regulations, the following apply:

- a) Implement requirements of the federal regulations governing the responsibility of the University and each individual researcher to promote the objectivity of research funded by PHS.
- b) Publish and disseminate standards that promote reasonable expectations that the design, conduct and reporting of research in PHS-funded grants, sub-grants or collaborative agreements will be free from the influence of the researcher's financial conflicts of interest.

## **1. Scope**

The instructions apply to all researchers and all research at KI, which is funded by PHS.

These instructions are to be interpreted in light of the US federal regulations set forth herein and all regulatory requirements set forth in PHS directives.

## 2. Definitions

**Disclosure of significant financial interests:** A researcher's disclosure of significant financial interests to KI.

**Financial conflict of interest (FCOI):** A significant financial interest that can directly and significantly affect the design, implementation and reporting of research funded by PHS.

**FCOI report:** KI's report of a financial conflict of interest to an organizational unit within PHS that makes contributions to the research.

**Economic interest:** Includes something of monetary value, whether or not the value can be determined.

**Institutional Responsibilities:** A researcher's professional responsibilities on behalf of KI, and as defined in this document, which may include activities such as research, research consultancy, teaching, professional practice, membership of institutional committees and/or expert groups such as institutional or data and safety monitoring boards.

**Researchers:** Project director (PD) or principal investigator (PI) and all other persons, regardless of title or position, who are responsible for the design, implementation and reporting of PHS-funded research, or proposals for such funding (can also include employees or consultants).

**Key person:** The researcher or any other person identified as a senior or key person by KI in the grant application, progress report, or other report submitted to PHS by the university under Title 42 CFR 50, Subpart F (Promoting Objectivity in Research) of the Code of Federal Regulations.

**PD/PI:** A project manager or principal researcher for a PHS-funded research project; PD/PI is included in the definition of senior/key person and researcher under this part.

**Subrecipient:** An organization or researcher participating in research together with the grant recipient university (e.g. subcontractors or consortium members).

**Governance/Management:** An action plan to address an FCOI, which may include strategies to reduce or eliminate the financial conflict of interest, to ensure that the design, conduct and reporting of the research is free of bias.

**PHS:** Abbreviation for the US Public Health Service. Department of Health and Human Services, which includes the National Institutes of Health (NIH).

**PHS Awarding Component:** The PHS organizational unit that funds the research covered by this component.

**Compliance & Data Office (CDO):** KI's administrative unit responsible for monitoring compliance with management plans for FCOIs.

**Research:** Scientific experimental or theoretical work or scientific studies through observation, if the work or studies are done to obtain new knowledge, and development work on a scientific basis. The term includes basic and applied research (e.g. a published article, book or book chapter) and product development (e.g. a diagnostic test or drug). Included in these instructions are any type of activity for which research funding is available from PHS through grants or cooperative agreements, including research grant, career development award, center grant, individual scholarship award, infrastructure award, institutional training grant, program project, or research resource award.

**Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of the researcher (including the researcher's spouse, common-law partner and/or minor children) that reasonably appear to be related to the researcher's institutional responsibilities:

- a) listed companies: a significant financial interest exists if the value of any compensation from the company in the twelve months preceding the disclosure and the value of an ownership interest in the company as of the date of the disclosure, when aggregated, exceeds \$5,000. In this definition, compensation is intended to include salary and any payment for services not otherwise identified as salary (eg consulting fees, royalties, paid writing); ownership interest includes shares, options or other ownership interests, which are determined by reference to public prices or other reasonable measures of fair market value.

- c) unlisted companies: a significant financial interest exists if the value of any remuneration received from the company in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the researcher (or the researcher's spouse/partner and/or minor children) hold their own share (e.g. shares, options, or other ownership interests).
- d) Intellectual property rights and interests (eg patents, copyrights) in the receipt of income related to such rights and interests.
- e) Reimbursed or sponsored travel (ie that paid on behalf of the researcher and not reimbursed to the researcher so the exact monetary value may not be readily available), related to their institutional responsibilities.

**Exceptions to significant financial interests:** SFIs do not include the following types of financial interests:

- a) Salary, royalties, or other compensation that the university pays the researcher if the researcher is currently employed or otherwise appointed by the university.
- b) Intellectual property rights assigned to the University and royalty sharing agreements related to such rights.
- c) Income from seminars, classes, or teaching engagements sponsored by a federal, state, or local agency, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic hospital, medical center, or research institute affiliated with an institution of higher education.
- d) Income from investment channels, such as mutual funds and retirement accounts, as long as the researcher does not directly control the investment decisions made in these channels.
- e) Income from serving on advisory committees or review panels for a federal, state, or local agency, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic hospital, medical center, or research institute affiliated with the institution of higher education.
- f) Travel that is reimbursed or sponsored by a federal, state, or local authority, an institution of higher education as defined in 20 U.S.C. 1001(a), an academic hospital, medical center, or research institute affiliated with the institution of higher education.



## 3. The researcher's and KI's responsibilities

### 3.1 The researcher's responsibilities

- Declare any significant financial interests.
- Provide updates to announced information as needed.
- If acting as PI/PD, provide a list of individuals who meet the definition of “researcher” within the required announcement timeline.
- Carry out the necessary training.
- Complete the annual FCOI form, even if you have no financial interests to report.
- Ensure that an updated FCOI form is available with the CDO before new research applications funded by PHS are submitted.

### 3.2 KI's responsibilities

- Maintain up-to-date, written, executed instructions on the FCOI that comply with the provisions of '42 CFR 50, Subpart F ', and make them openly available through the KI website.
- To inform each researcher of KI's instructions for FCOI, the researcher's responsibilities regarding disclosure of SFI and that each researcher must undergo mandatory training before participating in research related to PHS-funded grants. The training must be completed at least every four years.
- If KI conducts PHS-funded research through a “subrecipient” (eg, subcontractors or consortium members), KI must take reasonable steps to ensure that each “subrecipient” researcher complies with the federal regulations set forth in '42 CFR 50, Subpart F '.
- Designate case managers to collect and review notification of SFI from each researcher who plans to participate in or is participating in PHS-funded research.
- Inform every researcher who plans to participate in PHS-funded research that they must:
  - Report significant financial interests to the CDO at the latest at the time of application for PHS-funded research.
  - Submit updated information on SFI at least once a year, in accordance with the specific time period prescribed by KI, during the award period.

- Submit updated information on SFIs within thirty days of discovery or acquisition (eg by purchase, marriage or inheritance) of a new significant financial interest.
- Provide guidelines for determining whether a researcher's SFI is related to PHS-funded research and, if so, assessing whether the SFI is a financial conflict of interest (FCOI).
- Implement measures deemed necessary to manage FCOI, including possible financial conflicts with a "subrecipient", by developing and implementing an action plan.
- Provide initial and ongoing FCOI reports to PHS as required.
- Document and retain all researcher notifications of financial interests and KI's review of and response to such notifications (whether or not a notification resulted in a decision on an FCOI) and all actions taken under these instructions or upon retrospective review, if applicable, in at least three years from the date the final expenditure report is submitted to PHS or where appropriate.
- Establish administrative measures to ensure the researcher's compliance with these instructions.
- Certify, when appropriate, that KI's instructions and procedures are up-to-date and (i) through an administrative process identify and manage FCOIs in all PHS-funded projects; (ii) supports disclosure compliance for SFIs; (iii) manage initial and ongoing FCOI reports; (iv) provide information promptly upon request to HHS regarding financial interest disclosures, KI's review of and response to such disclosures in determining the FCOI; and (v) fully comply with the requirements of '42 CFR 50, Subpart F'.

## 4. Order of handling

At KI, there is an FCOI committee for identification, investigation, management and reporting of FCOI in PHS-funded research.

### 4.1 Members of the FCOI committee

The FCOI Committee consists of:

- the university director or whom the university director appoints,
- the general counsel or whom the general counsel appoints,

Karolinska Institutet – Instructions for managing financial conflicts of interest in research projects funded by US federal health agencies

- vice-president for research or vice-chairman of the Committee for Research,
- as well as the head of the Compliance & Data Office.

The head of department affected by the respective case will also be co-opted to the committee.

## **4.2 Notification of significant financial interests**

Researchers conducting research at KI must report all significant financial interests (SFI), which are relevant to the researcher's institutional research responsibility, to the CDO before participating in PHS-funded projects. The application must have been received at the latest when a research grant is applied for. The researcher must also report all SFIs within 30 days of becoming aware of a new SFI or of ending a financial conflict of interest for ongoing PHS-funded research. Notification of SFI must be reported annually. The researcher is responsible for completing the annual FCOI form even if they have no financial interest to report. New researchers joining an ongoing PHS-funded project are also obliged to report SFI to the CDO within 30 days of joining the research project.

## **4.3 Significant Financial Interest Review Process**

CDO performs an initial review of all SFI data. If necessary, the researcher is contacted for further information. The CDO determines which SFI cases may be considered a potential FCOI and refers the case to the FCOI Committee for review. The determination of an FCOI will be based on the following criteria:

- i. Description of the financial interest in relation between the researcher/relative and the external organisation.
- ii. Terms of sponsored project agreements that may reduce or increase risks.
- iii. Any damage to the integrity of the research data.
- iv. Risks to the rights and safety of animals and/or research subjects.
- v. Potential risks of conflicts of interest.

FCOI exists when the FCOI committee at KI reasonably determines that SFI can directly and significantly influence the design, implementation or reporting of the PHS-funded research.

#### **4.3.1 Review of new significant financial interests**

If a researcher in an ongoing PHS-funded project reports a new SFI to KI, the FCOI Committee will review the information within 60 days to determine whether the SFI is related to PHS-funded research and whether it constitutes an FCOI. In cases where FCOI occurs/is found, KI will draw up an action plan (section 6.3) and report the matter to the funder.

#### **4.3.2 Review of existing significant financial interests**

In cases where KI identifies an SFI that was not timely reported by a researcher under an ongoing PHS-funded project, the FCOI Committee shall review the SFI within 60 days to determine whether it is PHS-funded research and constitutes an FCOI. In cases where FCOI is identified, KI will develop an action plan (section 6.3) and report the matter to the PHS funder.

#### **4.3.3 Ex post review of significant financial interests**

There are certain events that could constitute non-compliance with KI's FCOI instructions, rules and procedures, requiring a retrospective review. These include:

- The researcher does not report an SFI that is determined to be an FCOI by KI.
- KI fails to review and manage an FCOI.
- The researcher does not follow an FCOI management plan.

If any of these situations occur, the FCOI Committee shall determine non-compliance and complete an ex-post review of the researcher's activities and the PHS-funded research project to determine whether any PHS-funded research, or part thereof, conducted during the period of non-compliance been biased in the design, conduct or reporting of such research. An ex-post review must be completed within 120 days of the non-compliance being identified.

## **4.4 Management of financial conflicts of interest**

In cases where FCOI is identified, an action plan will be drawn up by the FCOI committee in collaboration with the researcher and institution concerned. The terms of the action plan will be determined in accordance with national legislation.

## **4.5 Reporting requirements to NIH**

Prior to the disbursement of research funds within the PHS-funded project, KI shall, upon request, provide an FCOI report regarding any SFI found to be an FCOI. KI must provide an FCOI report within 60 days of the date a new SFI notification is determined to be an FCOI, a new researcher with an identified FCOI begins participating in the project, or when KI identifies an FCOI that was not previously notified. The report must contain the grant/contract number, PD/PI and name of the researcher with FCOI.

### **4.5.1 FCOI report**

In the FCOI report, KI must specify the nature of the FCOI (e.g. equity, consultancy fees, travel allowance or fee). The report must also contain the following information:

- The value of the economic interest or a statement of interests whose value cannot be determined by reference to public prices or other reasonable measures of existing market value.
- Description of how the FCOI relates to PHS-funded research and the rationale for the determination of the financial conflict of interest.
- Summary of the action plan.

### **4.5.2 Yearly FCOI report**

Upon request, KI must provide annual updates of the report throughout the duration of the research project. The annual report will include the status of the FCOI, changes to action plan(s) and justification if the FCOI no longer exists.

### **4.5.3 Updating the FCOI report**

Based on the results of the ex-post review, the KI shall, if appropriate, update the previously submitted FCOI report and specify the actions that will be taken to manage the financial conflict of interest going forward. Key elements that will be included in the updated report include grant/project

number, project title, PD/PI, name of researcher with FCOI, name of principal of FCOI, reason for the review conducted, methodology used for the review, results and conclusions of the review.

If bias is found in the review, according to US federal regulations, KI must submit a mitigation report. The mitigation report will consist of key elements identified in the retrospective review above, and a description of the impact of the bias on the research project and KI's action plan to eliminate or reduce the impact of the bias measures taken. Depending on the severity of the identified financial conflict of interest, KI may determine that additional interim measures are necessary with respect to the researcher's participation in the PHS-funded project between the date the FCOI or the researcher's non-compliance determination is made and the completion of KI's retrospective review.

Reports will be submitted to the NIH funder by uploading an initial (original) and annual FCOI report to eRA-commons in accordance with US federal regulations.

## **4.6 Requirements for subrecipients**

If a research project involves subrecipients, they must provide written assurance that they have a (local) policy or equivalent for handling financial conflicts of interest in research at that institution that complies with all applicable US federal regulations in accordance with the PHS. If the subrecipient does not have its own policy, a written agreement must be drawn up between KI and it stating that KI's instructions must also apply to the subrecipient.

## **4.7 Education requirements**

All KI researchers receiving PHS funding must complete mandatory FCOI training at the following intervals:

- Before participating in PHS-funded research and at least every four years thereafter.
- When these instructions are revised in any way that affects the researcher's requirements.
- When a researcher is new at KI (and will be part of a PHS-funded project).

Karolinska Institutet – Instructions for managing financial conflicts of interest in research projects funded by US federal health agencies

- When a researcher does not follow KI's instructions or management plan.

This training is mainly done via the CITI Program web training that KI provides for all researchers.

## **4.8 Documentation**

KI must preserve all documentation relating to the implementation of these instructions in accordance with Swedish law.

## **4.9 Requirements for public accessibility**

This document will be published on KI's public website. In addition, information on identified FCOIs held by senior/key personnel will be made available upon request via an email response within five working days.

A written response will include:

- Names of senior/key people
- The role of the senior/key person in the research project
- Name of the principal where the FCOI is held
- The nature of the FCOI
- Estimated dollar value of FCOI or a statement that the value cannot be determined