

University of Copenhagen Policy on Financial Conflicts of Interests applicable to awards or subawards issued from U.S. Public Health Services



16 JUNE 2021

RESEARCH & INNOVATION

NORREGADE 10, P.O.B. 2177
1165 COPENHAGEN K
DENMARK

DIR +45 35 33 26 10
MOB +45 29 13 26 10

kim.brinckmann@adm.ku.dk
www.fi.ku.dk/english

The University of Copenhagen (the Institution) will, in projects with awards or subawards issued from U.S. Public Health Services (PHS), comply with the requirements set forth in 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements, in order to ensure that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the Program Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. In this regard, the University of Copenhagen shall ensure that the following provisions are met:

- 1) There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which the National Institute of Health (NIH) funding is sought or received;
- 2) The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests (SFIs);
- 3) The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;
- 4) When requested, the Institution will promptly make information available to the NIH/The U.S. Department of Health and Human Services (HHS) relating to any Investigator disclosure of financial

interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;

- 5) The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.
- 6) The Institution must, for at least 3 years, retain all records of all Investigator disclosures of financial interests and the University's review, or response to, such disclosure (whether or not a disclosure resulted in determination of an FCOI), and all actions under our own policies or retrospective review,
- 7) The Institution shall fully comply with the requirements of the regulation by adhering to the below procedures.

Procedure regarding training

All PHS-funded Investigators are required to take training on conflicts of interest prior to engaging in NIH-supported research and at least every four years, as well as immediately under the designated circumstances:

- 1) Institutional FCOI policies change in a manner that affects Investigator requirements
- 2) An Investigator is new to an Institution
- 3) An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

The PD/PI must complete an NIH Office of Extramural Research tutorial on FCOI, as well as the quiz connected to the tutorial, which can be accessed at the following link:

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

Procedure in case of a Significant Financial Interest (SFI):

All Investigators must disclose any SFI with respect to their Institutional Responsibilities to their Institute Leader who will bring the case to the FCOI Board. The FCOI Board will determine whether such interest constitutes FCOI. Where an SFI is determined to be an FCOI, a management plan will be drawn up by the FCOI Board to help manage, reduce or eliminate the FCOI, and a disclosure of the FCOI and management plan must be submitted to the PHS-funder. Adherence to the management plan must be monitored. Before any expenditure of PHS funds, information concerning any disclosed SFI which has been determined to be an FCOI relating to

PHS-funded research, must be made publicly accessible by written response within 5 working days of request.

Composition of the FCOI Board

The FCOI Board shall consist of the Institute Leader at the institute where the researcher in question is employed, the Vice Director of Research and Innovation, the Vice Dean for Research at the researcher's faculty of employment, as well as an administrative official from the Office of Research Services at Research and Innovation.

For the avoidance of doubt, the FCOI Board described here relates only to projects which are bound by this Policy of Financial Conflicts of Interests, defined as projects with awards or subawards issued from U.S. Public Health Services.

Procedure in cases of non-compliance

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

The FCOI Board'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 FCOI Board, will be described in a written explanation of the decision to the Investigator. The Institution will promptly notify the NIH of the action taken or to be taken.

If the funding for the Research is made available from a prime NIH awardee, defined as the institution or other entity that is the signatory on the award and who is financially accountable for the use of the NIH funding provided for the performance of the project and is legally responsible for carrying out the terms and condition of the award, such notification shall be made promptly to the prime awardee for reporting to NIH.

In addition, if the FCOI Board 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 FCOI Board 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, PD/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 FCOI Board will update any previously submitted report to the NIH or the prime 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 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.

Procedure regarding reporting

When the Institution determines that an FCOI exists, the Institution must report to the NIH awarding Institute or Center (IC) through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:

- 1) Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
- 2) Name of Investigator (if different from the PD/PI) with the FCOI;
- 3) Name of the entity with which the Investigator has an FCOI;
- 4) Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- 5) Value of the financial interest \$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 a value cannot be readily determined;
- 6) A description how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- 7) Key elements of the Institution's management plan, including:
 - a) Role and principal duties of the conflicted Investigator in the research project;
 - b) Conditions of the management plan;

- c) How the management plan is designed to safeguard objectivity in the research project;
- d) Confirmation of the Investigator's agreement to the management plan;
- e) How the management plan will be monitored to ensure Investigator compliance; and
- f) Other information as needed.

The annual FCOI report must be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the FCOI no longer exists. The annual FCOI report will include the following information:

- 1) Status of the FCOI
- 2) Changes to the management plan, if applicable

The FCOI Board shall 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 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.

Procedure regarding subrecipients

The Institution will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the NIH to meet its reporting obligations.

Definition of PHS

The PHS comprises 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)

Policy regarding interpretation of these rules and procedures

Nothing in this policy shall be construed as being contradictory to the FCOI Regulation, 42 CFR 50, Subpart F, which can be found in its entirety at <https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

Further guidance relating to the FCOI Regulation can be found at the NIH Grants and Funding FAQ at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm> as well as the NIH FCOI External User Guide at https://era.nih.gov/files/fcoi_user_guide.pdf.

Yours sincerely,



Kim Brinckmann
Deputy Director
University of Copenhagen
Department of Research & Innovation

UNIVERSITY OF COPENHAGEN
16/6-2021
Research & Innovation
Nørregade 10
1165 Copenhagen K.

