The Capital Region of Denmark
Rigshospitalet, Research Support & Finance Unit

REGION H

Policy on Financial Conflicts of Interests

Applicable to awards or subawards issued from

U.S. Public Health Services

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1. Introduction

The Capital Region of Denmark will, in projects with awards or subawards issued from U.S. Public Health Services (PHS), comply with the requirements set forth in the FCOI regulation 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 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 Capital Region of Denmark shall ensure that the following provisions are met:

1) 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) Promotion and enforcement of Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests (SFIs)

3) Identification and management of FCOIs and provision of initial and ongoing FCOI reports to the NIH consistent with this subpart

4) When requested, the Capital Region of Denmark will 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 Capital Region of Denmark's review of, and response to, such disclosure, whether the disclosure resulted in The Capital Region of Denmark's determination of an FCOI

5) Making certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible website or written response to any requestor within five business days of a request and update such information as specified in the regulation

6) For at least 3 years from the date of submission of the final expenditures report retain all records of all Investigator disclosures of financial interests and the Capital Region of Denmark's review, or response to, such disclosure (whether a disclosure resulted in determination of an FCOI), and all actions under our own policies or retrospective review, or where applicable, from other dates specified in 45 C.F.R. 75.361

7) Fully comply with the requirements of the regulation by adhering to the below procedures.

2. Definitions

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

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

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

> *Financial Interest* does NOT include:
> a) salary, royalties, or other remuneration from the Institution
> b) income from the authorship of academic or scholarly works
> c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with U.S. institutions of higher education, academic teaching hospitals, and medical centers or
> d) 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 vehicles.
>
> For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with U.S. institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Institutional responsibilities, and:

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 (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Financial Conflict of Interest (FCOI) Board means the committee of the Capital Region of Denmark that recommends matters regarding conflict of interests. The committee will be designated by the Unit of Research Support and Finances when an SFI emerges. It will consist of the executive board member of The Capital Region of Denmark responsible for research at the hospital in question, The Medical Chief at the hospital department in question and the unit chief from Unit of Research Support and Finances.

Institutional official means the individual within the Institution responsible 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. In this case, the institutional official will comprise of the Research Support and Finance Unit.

Institutional responsibilities mean 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 PD/PI and any individual who is responsible for the design, conduct, or reporting of PHS 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.

Public Health Service (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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

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).

The Capital Region of Denmark is a Danish political organization with 1,9 Mio citizens dispersed into 29 municipalities (98 in all). Out of a total of 5 regions, The Capital Region of Denmark is the largest region managing 45.000 employees and 7 hospitals, in which approximately 92% of the budget is earmarked to deliver healthcare services.

The Research Support and Finance Unit is centralized within the organization of The Capital Region of Denmark, at service to all researchers within The Region in the phases of pre- and post-award in terms of national and international grants.

3. Conflict of Interest

This policy is predicated on the expectation that Investigators should conduct their affairs 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.

3.1 Disclosure of Financial Interests

Investigators are required to disclose their outside financial interests as defined above to the Capital Region of Denmark at the time of the application, on an annual and on an ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

Annual Disclosures

All Investigators must disclose their SFIs that are related to the investigator’s institutional responsibilities to the Institution, through the Institutional Official, on an annual basis (second quarter (Q2)).

Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. Prior to engaging in Public Health service sponsored projects, All Investigators must disclose their SFIs to the Institution, through the Institutional Official.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has an SFI, 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 SFIs 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 year within thirty (30) days of discovering or acquiring the SFI.

Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and SFI. 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 an FCOI with the Investigator's research.

3.2 Procedure in case of an SFI

If an SFI is revealed, the Institutional Official will appoint an FCOI Board to review and determine the necessary course of action. The FCOI Board is required to review all Investigators SFI disclosures in question, determine if any SFIs relates to PHS/NIH-funded research and whether an FCOI exists.

A Financial Conflict of Interest exists when the Institution, through its designated FCOI Board determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project (i.e., the Significant Financial Interest could be affected by the research or is the Significant Financial Interest in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research or is in an entity whose financial interest could be affected by the research. 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.

The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

3.3 Composition of the FCOI Board

To secure the insight into the part of the Capital Region of Denmark the investigator belongs to, the FCOI Board will comprise of members from the Hospital within which the investigator is employed and a consistent member throughout all FCOI boards from the Research Support Unit of The Capital Region of Denmark.

The members from the hospital in question will be:

1. The Hospital's member of the executive board of The Capital Region of Denmark responsible for research,
2. The Medical Chief at the department at the hospital in question,
3. The Unit chief from The Research Support and Finances Unit.

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.

3.4 Procedure on reporting

When the FCOI Board determines that an FCOI exists, the Institution Official will report to the NIH awarding Institute or Center (IC) through the submission of an initial and, thereafter an annual FCOI report (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) using the eRA Commons FCOI Module. The initial FCOI report, will be submitted prior to the expenditure of funds, within sixty (60) days of identifying an FCOI during the period of an award and/or identification for an Investigator who is newly participating in the project. 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 Capital Region of Denmark's determination that the financial interest conflicts with such research an

7) Key elements of the Capital Region of Denmark'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 will be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until The Capital Region of Denmark reports that the FCOI no longer exists. The annual FCOI report will until the conclusion of the project includes the following information:

1) Status of the FCOI

2) Changes to the management plan, if applicable

The FCOI Board shall report an FCOI 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 sixty (60) days of any subsequently identified FCOI 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.

In the case of identification of SFIs to be FCOIs for newly participating Investigators or existing Investigators disclosing new SFIs to the Institution official during the period of an ongoing NIH-funded research project, the Institution will submit an FCOI report within sixty (60) days after its determination that an FCOI exists.

3.5 Specific requirements related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of an FCOI involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

3.6 Procedure in cases of non-compliance

Disciplinary Action

In the event of an Investigator fails 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 Institutional official 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 Capital Region of Denmark 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.

Retrospective Review

In addition, if the FCOI Board determines that an FCOI was not disclosed, reviewed or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, or if the Institution fails to review or manage such an FCOI, the FCOI Board will within 120 days of the determination of non-compliance, 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 FCOI, name of the entity with which the Investigator has the FCOI, 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 awardee relating to the Research, specifying the actions that will be taken to manage the FCOI going forward. This retrospective review will be completed in the manner and within the timeframe established in NIH regulations. If bias is found, The

Capital Region of Denmark 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.

3.7 Procedure regarding subrecipients

The Capital Region of Denmark 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 FCOI to the awardee Institution within 45 days of any subsequently identified Conflict of Interest to allow the awardee institution to report the FCOI to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the awardee Institution's policy must submit all Investigator disclosures of Significant Financial Interests to the awardee no later than 30 days to allow the awardee to review, manage and report identified FCOIs to the NIH. In this regard, the Awardee Institution are responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

4. 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) FCOI policies of The Capital Region of Denmark change in a manner that affects Investigator requirements

2) An Investigator is new to The Capital Region of Denmark

3) The Capital Region of Denmark finds an Investigator noncompliant with the 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.

The PD/PI will receive information on the procedures and the FCOI Policy of the Capital Region of Denmark as well as his or her disclosure responsibility of all foreign and domestic SFI.

5. Public Accessibility

Prior to the expenditure of funds, the Institution will respond to any requestor within five business days of the request, information concerning any SFI 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 SFI is related to the PHS-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 PHS regulation.

6. 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

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