FINANCIAL CONFLICT OF INTEREST POLICY
UNIVERSITY OF HELSINKI

1. INTRODUCTION

This policy governing financial conflict of interest applies to all U.S. Public Health Service (hereinafter referred to as “PHS”) -sponsored Investigators of the University of Helsinki. The Director of the Department at the University of Helsinki (hereinafter referred to as the “Director of Department”) is responsible for ensuring the due implementation of this policy. In the event that the Director of Department is working as an Investigator in the PHS-sponsored research, the Vice-Rector who is responsible for the research affairs at the University of Helsinki will take care of the assignments and duties appointed in this policy.

The Director of Department may suspend all relevant activities related to the research in question until a financial conflict of interest is resolved or other action deemed appropriate by the Director of Department is implemented. Violation of any provision of this policy may also constitute cause for disciplinary or other administrative action pursuant to the policies of the University of Helsinki.

2. DEFINITIONS

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

2.2 Family member means the Investigator’s dependent children and spouse.

2.3 Financial Interest means anything of monetary value received or held by an Investigator or an Investigator’s Family member, whether or not the value is readily ascertainable. Financial Interest includes, but is 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); intellectual property rights (e.g., patents, trademarks, and copyrights), and received royalties or other income related to such intellectual property rights.

2.4 Financial Interest does not include:

   a) salary, royalties, or other remuneration from the University of Helsinki or the Hospital District of Helsinki and Uusimaa (HUS);

   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 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.

2.5 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 institutions of higher education, academic teaching hospitals, medical centers, University of Helsinki or the Hospital District of Helsinki and Uusimaa.

2.6 Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

a) with regard to a publicly traded entity:

the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, or the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds $5,000; or

b) with regard to 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) with regard to a non-publicly traded company:

there 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 University of Helsinki or the Hospital District of Helsinki and Uusimaa; or

e) is reimbursed or sponsored travel related to Investigator’s institutional responsibilities.

2.7 Financial Conflict of Interest means a Significant Financial Interest (or, where the Director of Department requires disclosure of other Financial Interests, a Financial Interest) that the University of Helsinki reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

2.8 The Director of Department means the director of the department performing research at the University of Helsinki who is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family members related to the Investigator’s Institutional Responsibilities.

2.9 Institutional Responsibilities mean the Investigator’s professional responsibilities associated with his or her appointment or position in the University of Helsinki, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee
services that are related to the operation of the University of Helsinki or the Hospital District of Helsinki and Uusimaa, regardless of whether a salary is paid to the Investigator or not.

2.10 Investigator means 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, or graduate students. The definition may also include collaborators or consultants as appropriate.

2.11 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.

2.12 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).

3. CONFLICT OF INTEREST

This policy is predicated on the expectation that 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 the Investigators and the University of Helsinki to manage those conflicts of interest that arise, and describes situations that are prohibited under the provisions of this policy. Every Investigator conducting or involved in PHS-sponsored research 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 needs to discuss the situation with the Director of Department.

4. DISCLOSURE OF FINANCIAL INTERESTS

All Investigators of University of Helsinki, who are involved in PHS-sponsored research, are required to disclose their outside financial interests as defined above to the University of Helsinki on an annual and on an ad hoc basis, as described below. The Director of Department is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

4.1 Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the Investigator’s Institutional Responsibilities to the University of Helsinki, on an annual basis. All disclosure forms shall be submitted by a date informed by the University of Helsinki.

4.2 Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to University of Helsinki within thirty (30) days of
their initial appointment or employment. The disclosure forms shall be submitted to the Director of Department.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Director Of Department an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Investigator is not allowed to submit a project plan for the application unless she or he has submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Director of Department 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.

4.3 Travel

Investigators must also disclose, according to University of Helsinki Instructions for Travel, 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 Director of Department will determine if additional information is needed to determine whether the reimbursed or sponsored travel constitutes a Financial Conflict of Interest with the Investigator’s research.

5. REVIEW AND DECISION OF THE DIRECTOR OF DEPARTMENT AND THE DIRECTOR OF RESEARCH AFFAIRS

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Director of Department together with the Director of Research Affairs for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Director of Department will take action that is deemed appropriate to manage the financial conflict of interest.

A Financial Conflict of Interest will exist when the Director of Department after negotiations with the Director of Research Affairs determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Director of Department determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement, in cooperation with the Investigator and the Director of Research Affairs, a written management plan. The purpose of the management plan is to eliminate the conflict of interest resulting from existing Significant Financial Interest and to try to remove the problems and disadvantages caused by it. 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.

The Director of Department and the Director of Research Affairs will periodically review the ongoing activity and monitor the conduct of the activity to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

6. CLINICAL RESEARCH

Clinical research involves particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.
In the event of non-compliance with reporting and the terms of this policy in a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, 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 about the financial conflict of interests to previously published presentations.

7. REPORTING TO PHS

The Director of Department will be responsible for reporting Financial Conflicts of Interest or non-compliance of this policy to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-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 financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

8. NON-COMPLIANCE

If an Investigator neglects to comply with this policy, the Director of Department may suspend all relevant research activities or take other disciplinary action until the Financial Conflict of Interest is resolved or other action deemed appropriate is implemented.

If an Investigator has neglected to comply with this policy, or the management plan made together by the Director of Department, the Director of Research Affairs and the Investigator as described in section 5, the Investigator shall be notified of a decision of the Director of Department to impose possible sanctions according to the standard procedures of the University of Helsinki. Before this decision is made the Director of Department will consult the Director of Research Affairs. The decision with necessary reasoning shall be given to the Investigator in writing. The University of Helsinki will promptly notify PHS of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

8.1 Retrospective Review

If the Director of Department determines after consulting the Director of Research Affairs that a Financial Conflict of Interest was not identified or managed in a timely manner, it is possible to complete a retrospective review of the Investigator’s activities and the PHS-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. In addition, the retrospective review is possible in a situation of 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.

Documentation of the retrospective review shall include the project number, project title, principal investigator, 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 Director of Department will update any previously submitted report to the PHS or the prime PHS-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 PHS regulations. If bias is found, the University of Helsinki will promptly notify PHS and the prime PHS awardee and submit a mitigation report in accordance with the PHS 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.

9. TRAINING

Each Investigator of the University of Helsinki who is involved in PHS-sponsored research must complete training on this policy, the Investigator’s responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four (4) years thereafter. The Investigators must also complete training within a reasonable period of time as determined by the Director of Department 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 University of Helsinki, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

10. RECORD RETENTION

The Director of Department will retain all disclosure forms, conflict management plans, and related documents for a period of three (3) years from the date the final expenditure report is submitted to PHS or to the prime PHS awardee. If any litigation, claim, financial management review, or audit is started before the expiration of the three (3) year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

11. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the University of Helsinki may be required to make such information available to PHS, or to the prime PHS awardee, if requested or required or to a person requesting or requiring information regarding a financial conflict of interest in PHS-sponsored research. If the University of Helsinki is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of such disclosure.

12. PUBLIC ACCESSIBILITY

The information concerning any Significant Financial Interest will be published according to the requirements of the PHS regulation.

13. REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.