

HOSPITAL DISTRICT OF SOUTHWEST FINLAND

Financial Conflicts of Interest in Research Funded by the U.S. Public Health Service (including NIH grants)

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1. Scope of the Guidelines

These guidelines on the financial conflicts of interest are applied to all Investigators at the Hospital District of Southwest Finland who participate in projects funded by the U.S. Public Health Service (PHS).

Chief Physician of Research at the Hospital District of Southwest Finland is in charge of the implementation of these guidelines. In a project funded by the PHS where the Chief Physician of Research works as an Investigator, the Chief Medical Officer is in charge of the tasks and responsibilities of the Chief Physician of Research listed in these guidelines.

2. Definitions

2.1 *Clinical research* means any PHS funded project where drugs, research equipment, medical device or medical or other clinical methods, such as surgery, are tested on a group of people.

2.2 *Significant financial interest* means any financial interest that reasonably appears to be related to the Investigator's institutional responsibilities and when

a) the Investigator receives benefits from a publicly or non-publicly traded entity, the total sum of the salary or remuneration received from the entity or the value of any

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- equity interest in the entity at the time of the disclosure or in the twelve months preceding the disclosure exceeds €4,000, or it exceeds \$5,000 according to the exchange rate upon receiving the income; or
- b) the Investigator receives remuneration from a non-publicly traded entity, when the Investigator holds or has held any equity interest in the twelve months preceding the disclosure or at the time of the disclosure, regardless of the value of the equity; or
 - c) the Investigator has intellectual property rights or interests related income that has not been received from the Hospital District of Southwest Finland or the University of Turku and the income exceeds €4,000, or it exceeds \$5,000 according to the exchange rate upon receiving the income; or
 - d) a travel cost related to the Investigators institutional responsibilities is reimbursed or sponsored.

A significant financial interest does not mean:

- e) salary, royalties or other remuneration paid by the Hospital District of Southwest Finland or the University of Turku;
- f) income from academic or scientific publications;
- g) income from seminars, lectures or teaching engagements sponsored by Finnish or American Federal, state or local government agency's advisory committees or review panels, higher education institutions and research institutions affiliated with a higher education institution, academic teaching hospitals and medical centers or
- h) from stakeholders' equities or other investment instruments, such as income from investment funds and pension funds, provided that the Investigator does not directly manage the decision making of these investment instruments.

2.3 *Family member* means the Investigator's dependent children and spouse.

2.4 *PHS* means the Public Health Service of the U.S. Department of Health and Human Service (HHS) and all other units that the PHS can authorize to manage its tasks. These units include e.g. 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.

2.5 *Financial interest* means any monetary benefit that the Investigator or their family member has received or possesses, whether or not the value is readily ascertainable. Financial interest means, among other things, salary or remuneration (e.g. consultation remuneration, ex gratia payment or remuneration for non-scientific publications), capital income, equity interest (e.g. stock, stock option and other ownership interest), intellectual property rights and interests (e.g. patents, trademarks and copyrights) and received royalties and other corresponding income related to intellectual property rights.

Financial interest also means any travels related to the Investigator's institutional responsibilities that have been reimbursed or sponsored for the Investigator, even if the exact monetary value of the travels is not readily available.

Financial interest does not mean travel expenses reimbursed or sponsored for the Investigator by Finnish or American Federal, state or local government agency's advisory committees or review panels, Finnish or American higher education institutions and research institutions affiliated with higher education institutions, academic teaching

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hospitals and medical centers, the Hospital District of Southwest Finland or the University of Turku.

- 2.6 *Financial conflict of interest (FCOI)* means any type of significant financial interest that the Hospital District of Southwest Finland sees as directly and significantly affecting the design, conduct or reporting of research funded by the PHS.
- 2.7 *Investigator* means any person who is responsible for the design, conduct or reporting of research funded by the PHS or has applied for PHS funding for their research. Investigator can also mean postdoctoral researchers or doctoral candidates.
- 2.8 *Research* means all systematic investigation, study or scientific experiment designed to develop generalizable knowledge relating broadly to public health, including behavioral and socio-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).
- 2.9 *Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Hospital District of Southwest Finland, such as research, teaching, clinical procedures, administrative tasks and internal and external institutional committee memberships related to the operation of the Hospital District of Southwest Finland and the University of Turku, regardless whether or not the Investigator receives any remuneration for these responsibilities.

3. Preventing Financial Conflicts of Interest

These guidelines are based on a principle according to which the Investigators must conduct their institutional responsibilities so that financial conflicts of interest are prevented or as few as possible arise. If financial conflicts of interest arise, they must be dealt with correctly.

These guidelines inform Investigators of situations related to research activities where conflicts of interest may arise and the guidelines bring forward procedures which the Investigators and the Hospital District of Southwest Finland can utilize in solving the conflicts of interests. In addition, these guidelines provide descriptions of procedures that are forbidden.

Every Investigator participating in a PHS funded research project, must study these guidelines and comply with the listed regulations. If a conflicts of interests arises, the Investigator must discuss it with the Chief Physician of Research.

4. Disclosure of Significant Financial Interests

4.1 Obligation to Disclose

Investigators at the Hospital District of Southwest Finland, who are involved in PHS funded research, are obligated to disclose all their external financial interests to the Hospital District of Southwest Finland annually and in certain situations described below:

The Chief Physician of Research is in charge of the distribution, receiving, handling, evaluation and retention of the disclosure documents. The disclosure documents have to be recorded.

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4.2 Annual Disclosures

All Investigators must annually disclose any major financial interests related to their institutional responsibilities to the Hospital District of Southwest Finland. Annual disclosures are submitted to the Chief Physician of Research by 31 December.

4.3 Disclosures in Separately Defined Situations

In addition to the annual disclosure, the Investigator must report any significant financial interest to the Hospital District of Southwest Finland within 30 days of the beginning of their employment relationship. The disclosure document is submitted to the Chief Physician of Research.

If the Investigator has neglected the annual disclosure, they must provide the Chief Physician of Research with an updated disclosure prior to leaving the research plan when applying for funding.

In addition, the Investigator must provide the Chief Physician of Research with a disclosure of any significant financial interest they have received or identified during the year, within 30 days of receiving or identifying such interest.

4.4 Travel

Those travels that are related to the Investigator's institutional responsibilities and have been reimbursed or sponsored for the Investigator have to be disclosed according to the Hospital District of Southwest Finland travel regulations. The disclosure on travel expenses must include, at a minimum, the purpose of the trip, destination, duration, the identity of the organiser or sponsor as well as the monetary value of the trip if readily available. If necessary, the Chief Physician of Research can request further information in order to determine whether the received travel compensations constitute a financial conflict of interest.

5. Responsibilities of the Chief Physician of Research

If the disclosure contains a significant financial interest, the Chief Physician of Research assesses together with the Chief Financial Officer whether the financial interest leads to financial conflict of interest. Financial conflict of interest exists when, after hearing the Chief Financial Officer, Chief Physician of Research determines that the significant financial interest can directly and significantly affect the design, conduct or reporting of research funded by the PHS.

When a financial conflict of interest has been identified, the Chief Physician of Research has to take action to manage it. The participation of the Investigator in the research funded by the PHS can be discontinued when the financial conflict of interest has been identified.

If the financial conflict of interest can be managed, the Chief Physician of Research designs and implements a written management plan in collaboration with the Investigator and the Chief Financial Officer. The purpose of the plan is to manage the financial conflict of interest arising from the significant financial interest and to eliminate the bias caused by it. The Investigator has to provide a written agreement to the management plan before they can continue in the research project funded by the PHS if their participation has been discontinued.

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6. Reporting to PHS

The Chief Physician of Research reports a financial conflict of interest or a failure to comply with these guidelines to the PHS according to their regulations. The report has to be disclosed prior to the expenditure of funds and within 60 days of any subsequently identified financial conflict of interest.

Before the expenditure of the PHS funds, the Chief Physician of Research has to disclose a report to the funder on the Investigator's significant financial interest and the actions the Hospital District of Southwest Finland has taken in the matter. Reporting is not necessary when the identified financial conflict of interest has been managed before the expenditure of funds.

When an Investigator's significant financial interest is identified during the project and it is in conflict with the FCOI report disclosed before the project, the Chief Physician of Research provides the FCOI report to PHS within 60 days of identifying the conflict and takes action to manage the financial conflict of interest. This provision also applies to situations where a new Investigator joins an ongoing project.

7. Failure to Comply with the Guidelines

7.1 Failure to Comply with the Guidelines during a Project

If the Investigator fails to comply with the regulations of these guidelines, the Chief Medical Officer can discontinue the ongoing research project or take other disciplinary actions until the bias related to the financial conflict of interest is solved or some other necessary measures are taken.

If the Investigator has neglected these guidelines or the management plan designed by the Chief Physician of Research, Chief Financial Officer and Investigator pursuant to Section 5, the Chief Medical Officer decides on further action, such as the consequences to the Investigator, after hearing the Chief Physician of Research and Chief Financial Officer and following hospital's usual procedure. The decision of the Chief Medical Officer on the consequences has to be given in writing and with justifications to the Investigator. In addition, the Hospital District of Southwest Finland has to immediately inform PHS of the actions that have or will be taken.

The Chief Medical Officer can discontinue all the activities related to the ongoing research or research project until the financial conflict of interest has been managed or when some other actions deemed appropriate by the Chief Physician of Research have been taken.

7.2 Retrospective Review

If after hearing the Chief Financial Officer, the Chief Physician of Research determines that the financial conflict of interest has not been reported or not been reported in time, the Investigator's activities and the research project funded by the PHS can be reviewed retrospectively and it can be investigated whether the failure to comply with the guidelines has biased the design, conduct or reporting of the research. Retrospective review is also possible when the Investigator has failed to disclose a significant financial interest that is determined to constitute a financial conflict of interest or when the Investigator has failed to comply with the management plan for the financial conflict of interest.

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The documents of the retrospective review has to include the project number, project title, principal Investigator, name of the Investigator with the financial conflict of interest, name of the entity with which the Investigator has a financial conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review as well as the findings and conclusions of the review.

The Chief Physician of Research has to update the previous reports that have been already disclosed to PHS, specifying the actions that will be taken to manage the financial conflict of interest. The retrospective review has to be disclosed within 120 days of identifying the financial conflict of interest. If the retrospective review reveals conflicts with the previous FCOI report, the Hospital District of Southwest Finland has to report the conflict without delay and disclose a mitigation report to PHS according to their regulations. The mitigation report must include the observations and measures that have been documented in the retrospective review, description of the impact of the bias on the research as well as a plan of action or actions taken which are considered necessary to remove or mitigate the effect of the bias.

8. Failure to Comply with the Guidelines in Clinical Research

Particularly sensitive issues can be involved in clinical research projects, which are determined by the U.S. Department of Health and Human Service (HHS) and funded by PHS, and whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment.

In these types of projects, the Investigator must disclose the financial conflict of interest in each public presentation of the research results if they have failed to disclose the financial conflict of interest to the Chief Physician of Research according to these guidelines and have nonetheless participated in the design, conduct or reporting of research funded by PHS. In addition, they have to request a similar addendum to all previously published reports and publications.

9. Training

Before engaging in a research project funded by PHS, the Investigator has to complete a training concerning these guidelines, Investigator's responsibility to disclose significant financial interests, and regulations of PHS. The training has to be completed at least every four years.

In addition, Investigators have to complete the training within a reasonable period defined by the Chief Physician of Research when:

- these guidelines are revised in a manner that affects the requirements of Investigators;
- the Investigator is new to the Hospital District of Southwest Finland; or
- it is discovered that the Investigator has not complied with these guidelines or the management plan for the financial conflict of interest.

10. Retention of Documents

The Chief Physician of Research retains all disclosures, management plans for financial conflicts of interest, and documents related to these for three years from the date when the final expense report of the project was disclosed to PHS. If legal proceedings, claim for compensation, assessment process regarding management of finances or an

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audit have been initiated on the financial interest or significant financial interest before the three-year period ends, the documents have to be retained until the process in question has ended and a final decision has been made in the matter.

11. Confidentiality

The confidentiality of all the disclosures, management plans for financial conflicts of interest, and documents related to these has to be maintained to the extent permitted by the law. However, the Hospital District of Southwest Finland might have to disclose information when requested or demanded by PHS or by a party requesting or demanding information on a financial conflict of interest related to PHS funding. If disclosures, management plans for financial conflicts of interest, and documents related to these are requested from the Hospital District of Southwest Finland by outsiders, the Investigator has to be informed of the disclosure.

12. Publishing Information on FCOI

Information on financial conflicts of interest is published according to the regulations of PHS.

13. Applicable Regulations

These guidelines implement the requirements put forth in the following PHS regulations:

- Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and
- Responsible Prospective Contractors (45 C.F.R. Part 94).

If the regulations in these guidelines and those of the U.S. Public Health Service are in conflict, the regulations of PHS are primary.

Mikko Pietilä
Chief Medical Officer