

University of Antwerp Financial Conflict of Interest Policy related to research funded by the United States Public Health Services

1. Purpose and scope of application

The present Financial Conflict of Interest Policy related to research at UAntwerpen funded by the United States Public Health Services (PHS) (hereinafter: "UAntwerpen PHS FCOIP") implements United States PHS regulation 42 CFR 50 Subpart F "Promoting objectivity in research"¹. Said regulation is applicable to each institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and to each Investigator who is planning to participate in, or is participating in, such research.

In accordance with the goals of PHS regulation 42 CFR 50 Subpart F, the purpose of the UAntwerpen PHS FCOIP is to promote objectivity in research and in particular to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

The UAntwerpen PHS FCOIP applies to all PHS-funded research at UAntwerpen and the Institution's Investigators involved therein. If UAntwerpen carries out PHS-funded research through a subrecipient (e.g. subcontractors or consortium members), UAntwerpen is also expected to take reasonable steps to ensure that any subrecipient Investigator complies with PHS regulation 42 CFR 50 Subpart F.

2. Definitions

For the application of the UAntwerpen PHS FCOIP the following definitions apply:

<i>Disclosure of significant financial interests</i>	an Investigator's disclosure of significant financial interests to UAntwerpen.
<i>Financial conflict of interest (FCOI)</i>	a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
<i>FCOI report</i>	UAntwerpen's report of a financial conflict of interest to a PHS Awarding Component.
<i>Financial interest</i>	anything of monetary value, whether or not the value is readily ascertainable.
<i>HHS</i>	the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
<i>Institution</i>	UAntwerpen, when applying for, or receiving PHS research funding.

¹ <https://www.law.cornell.edu/cfr/text/42/part-50/subpart-F>

<i>Institutional responsibilities</i>	an Investigator's professional responsibilities on behalf of UAntwerpen, including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
<i>Investigator</i>	the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
<i>Manage</i>	taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
<i>PD/PI</i>	a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under PHS regulation 40 CFR 50 Subpart F.
<i>PHS</i>	the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the United States National Institutes of Health (NIH).
<i>PHS Awarding Component</i>	the organizational unit of the PHS that funds the research that is subject to this subpart.
<i>Public Health Service Act or PHS Act</i>	the statute codified at 42 U.S.C. 201 et seq.
<i>Research</i>	a systematic investigation, study or experiment designed to develop or 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 term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
<i>Senior/key personnel</i>	the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS by UAntwerpen under Public Health Services (PHS) regulation 40 CFR 50 Subpart F
<i>Significant Financial Interest</i>	<p>(1) An investigator should disclose any financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:</p> <ul style="list-style-type: none"> • With regard to any publicly traded entity, a <i>significant financial interest</i> exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as

	<p>determined through reference to public prices or other reasonable measures of fair market value;</p> <ul style="list-style-type: none"> • With regard to any non-publicly traded entity, a <i>significant financial interest</i> exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or • Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. <p>(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (<i>i.e.</i>, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a United States Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. <u>Note:</u> Only the occurrence of reimbursed or sponsored travel needs to be disclosed on the disclosure form. In case of such disclosure the designated institutional officials will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.</p> <p>(3) The term <i>significant financial interest</i> does <u>not</u> include the following types of financial interests:</p> <ul style="list-style-type: none"> • salary, royalties, or other remuneration paid by UAntwerpen to the Investigator if the Investigator is currently employed or otherwise appointed by UAntwerpen, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights, and similar payments made by FWO, VLAIO and Flemish or Belgian public agencies or public knowledge institutions. • income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; • income from seminars, lectures, or teaching engagements sponsored by or from service on advisory committees or review panels for a United States Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a) , an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education.
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3. Training of Investigators

UAntwerpen will inform each Investigator planning to apply for or participating in PHS-funded research of UAntwerpen PHS FCOIP, the Investigator's responsibilities regarding disclosure of significant

financial interests, and of PHS regulation 40 CFR 50 Subpart F, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- UAntwerpen revises UAntwerpen PHS FCOIP or procedures in any manner that affects the requirements of Investigators;
- An Investigator is new to UAntwerpen; or
- UAntwerpen finds that an Investigator is not in compliance with UAntwerpen PHS FCOIP or the management plan.

4. Disclosure, assessment and management of financial conflicts of interest

In brief: Every Investigator applying for or involved in PHS-funded research is subject to the PHS regulation 40 CFR 50 Subpart F “Promoting objectivity in research”, as implemented by the present UAntwerpen PHS FCOIP. He/she is thereby required to disclose his/her financial interests related to the PHS-funded project. This should be done using a prescribe form. The form should be sent to the head of the department of Research & Innovation (ADOC). The disclosed financial interests will be assessed by UAntwerpen ‘s designated institutional official: the head of department of the department of Research & Innovation (ADOC). If a financial conflict of interest is identified, proper measures will be taken to mitigate the conflict.

4.1 Who should disclose and when?

1. Each Investigator who is planning to participate in the PHS-funded research should disclose to UAntwerpen ‘s designated officials his/her significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
2. Each Investigator who is participating in the PHS-funded research is required to submit
 - an updated disclosure of significant financial interests at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest)
 - an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
3. If UAntwerpen carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), UAntwerpen shall incorporate as part of a written agreement with the subrecipient terms that establish whether UAntwerpen PHS FCOIP or the Financial Conflicts of Interest Policy of the subrecipient will apply to the subrecipient’s Investigators.
 - If the subrecipient’s Investigators must comply with the subrecipient’s Financial Conflicts of Interest Policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with PHS regulation 42 CFR 50 Subpart F. If so, in addition, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to UAntwerpen. Such time period(s) shall be sufficient to enable UAntwerpen to provide timely FCOI reports*, as necessary, to the PHS.

- If the subrecipient cannot provide the required certification as to compliance of its policy with PHS regulation 42 CFR Part 50 Subpart F, the agreement shall state that subrecipient Investigators are subject to the present UAntwerpen PHS FCOIP for disclosing significant financial interests that are directly related to the subrecipient's work for UAntwerpen. Moreover, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to UAntwerpen. Such time period(s) shall be sufficient to enable UAntwerpen to comply timely with its review, management, and reporting obligations* under PHS regulation 42 CFR Part 50 Subpart F.

* i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

4.2 Disclosure by investigator

Every Investigator applying for or involved in PHS-funded research is required to disclose his/her financial interests related to the PHS-funded project by filling out a prescribed form. The form should be sent to the head of the Department of Research & Innovation (ADOC).

UAntwerpen will maintain records relating to all Investigator disclosures of financial interests and UAntwerpen 's review of, and response to, such disclosures (whether or not a disclosure resulted in UAntwerpen 's determination of a financial conflict of interest) and all actions under UAntwerpen 's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) en 92.42(b) for different situations.

4.3 Assessment of disclosed significant financial interests

The designated institutional official, i.e. the head of the Department Research & Innovation will solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

The designated institutional official will determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest.

- An Investigator's significant financial interest is related to PHS-funded research when UAntwerpen, through its designated officials, reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. UAntwerpen may involve the Investigator in the designated officials' determination of whether a significant financial interest is related to the PHS-funded research.
- A financial conflict of interest exists when UAntwerpen, through its designated officials, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

4.4 Management of identified financial conflicts of interest

Prior to the expenditure of any funds under a PHS-funded research project and within 60 days of the identification of the financial conflict of interest the designated officials shall,

- review all Investigator disclosures of significant financial interests;

- determine whether any significant financial interests relate to PHS-funded research;
- determine whether a financial conflict of interest exists; and,
- if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Examples of conditions or restrictions that might be imposed to manage the financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
- Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest, the designated official shall, within sixty days:

- review the disclosure of the significant financial interest;
- determine whether it is related to PHS-funded research;
- determine whether a financial conflict of interest exists; and,
- if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, UAntwerpen may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of UAntwerpen 's review.

Whenever a significant financial interest is being identified that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by UAntwerpen during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated officials shall, within sixty days:

- review the significant financial interest;
- determine whether it is related to PHS-funded research;
- determine whether a financial conflict of interest exists; and,
- if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by UAntwerpen to constitute a financial conflict of interest; failure by UAntwerpen to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, UAntwerpen shall, within 120 days of UAntwerpen's determination of

noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Based on the results of the retrospective review, if appropriate, UAntwerpen shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, UAntwerpen will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component, including the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and UAntwerpen's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, UAntwerpen will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, UAntwerpen may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of UAntwerpen's retrospective review.

4.5 Reporting of financial conflicts of interest

Prior to the expenditure of any funds under a PHS-funded research project, UAntwerpen shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by UAntwerpen to be conflicting and ensure that UAntwerpen or a concerned subrecipient adhering to UAntwerpen PHS FCOIP has implemented a management plan in accordance with UAntwerpen PHS FCOIP. In cases in which UAntwerpen identifies a financial conflict of interest which is being eliminated prior to the expenditure of PHS-awarded funds, no FCOI report will be submitted to the PHS Awarding Component.

For any significant financial interest that UAntwerpen identifies as conflicting subsequent to the UAntwerpen's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), UAntwerpen shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that UAntwerpen or a concerned subrecipient adhering to UAntwerpen PHS FCOIP has implemented a management plan. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by UAntwerpen (e.g., in case it was not timely reviewed or reported by a subrecipient), UAntwerpen will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, UAntwerpen will notify the PHS Awarding Component and submit a mitigation report.

For any financial conflict of interest previously reported by UAntwerpen with regard to an ongoing PHS-funded research project, an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project will be provided. The annual FCOI report specifies whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. UAntwerpen will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

In accordance with PHS regulation 40 CFR 50 Subpart F, UAntwerpen may have to ensure public accessibility of information concerning any significant financial interest disclosed to UAntwerpen that meets the following three criteria:

- The significant financial interest was disclosed and is still held by the Investigator;
- UAntwerpen determines that the significant financial interest is related to the PHS-funded research; and
- UAntwerpen determines that the significant financial interest is a financial conflict of interest.

4.6 Appeal

Investigators who do not agree with the designated institutional officials' finding that a FCOI exists or who do object to the proposed management plan, may, within fourteen calendar days after being informed of the contested decision, submit an appeal to the Executive Council of the UAntwerpen by means of an email addressed to the rector.

Appeals will be dealt with during the next regular session of the concerned executive board and will suspend the execution of the proposed management plan, though only provided that the above-mentioned conditions and time limits are not exceeded. Otherwise the management plan has to be implemented, on at least an interim basis. The Rector shall communicate the decision of the Executive Council to the applicant via email within fourteen calendar days.