

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT
FOR FACULTY AND INVESTIGATORS

Appendix C

Additional Requirements for PHS Research Proposals and Awards

This Appendix C to the Policy sets forth certain requirements that apply to PHS research proposals and awards (including grants, cooperative agreements, and contracts).¹ These requirements supplement any Investigator or University obligations under the Policy itself. To the extent of any conflict between a provision of the Policy and a provision of this Appendix C, the provision of this Appendix C shall govern.

Definitions

For purposes of this Appendix C, the following definitions apply.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the University, which may include for example: activities such as research, research consultation, teaching, professional practice, University committee memberships, and service on panels such as Institutional Review Boards or data and safety monitoring boards.

“Investigator” means 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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.

“PHS Awarding Component” means the organizational unit within PHS that funds the research that is subject to this Appendix C.

“Research” means 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, cooperative agreement, or contract, 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.

“Significant Financial Interest”² means, in addition to the interests described in Section III.A of the Policy, a financial interest³ consisting of one or more of the following interests of the

¹ See 42 CFR Part 50, Subpart F, “Promoting Objectivity in Research,” and 45 CFR Part 94, “Responsible Prospective Contractors.” Appendix C does not apply to Small Business Innovation Research Program (including Small Business Technology Transfer Program) Phase I applications.

² Nothing in this Appendix C imposes an obligation beyond that required by the Policy to disclose the following types of financial interests: (1) salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights; (2) income from

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(a) With regard to any *publicly traded entity*, a Significant Financial Interest 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 determined through reference to public prices or other reasonable measures of fair market value;

(b) With regard to any *non-publicly traded entity*, a Significant Financial Interest 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/domestic partner or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest);

(c) Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests; or

(d) the occurrence of any reimbursed or sponsored travel.⁴

Financial Disclosures by Investigators

In addition to the disclosure obligations set forth in Section III.B and C of the Policy, each Investigator planning to participate in PHS-funded research must disclose to the dean or the dean's designee the Investigator's Significant Financial Interests (and those of the Investigator's spouse/domestic partner and dependent children) no later than the time of application for the PHS-funded research.

Each Investigator participating in PHS-funded research must update his or her disclosure annually during the period of the award to reflect any information not disclosed initially or updates to any previously-disclosed Significant Financial Interests (*e.g.*, the updated value of

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; (3) income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; (4) income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or (5) travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

³ A financial interest is anything of monetary value, whether or not the value is readily ascertainable.

⁴ Sponsored travel means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator (so that the exact monetary amount may not be readily determined). The disclosure of reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

previously disclosed equity interests). Investigators are also required to report a new Significant Financial Interest within 30 days of discovering or acquiring the interest.

Review and Management of Financial Disclosures

Investigators' disclosures of Significant Financial Interests under this Appendix C must be reviewed by the dean or the dean's designee. Such review shall include a determination of whether an Investigator's Significant Financial Interest is related to a PHS-funded research project at the University and, if so, whether the Significant Financial Interest constitutes a financial conflict of interest.

An Investigator's Significant Financial Interest is related to PHS-funded research when (a) the Significant Financial Interest could be affected by the PHS-funded research or (b) the Significant Financial Interest is in an entity whose financial interest could be affected by the research.

A financial conflict of interest exists when an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research. The University will take such actions as are necessary to manage financial conflicts of interest in PHS-funded research, including, prior to the expenditure of PHS award funds, development and implementation of a management plan that specifies the actions that have been or will be taken to manage, reduce or eliminate the financial conflict of interest.⁵ Management plans must be approved by the dean (or designee) and the Provost and Executive Vice President.

Whenever, in the course of an ongoing PHS-funded research project, a Significant Financial Interest is disclosed by a new Investigator or an existing Investigator discloses a Significant Financial Interest not previously reported, or it comes to the attention of University officials that a Significant Financial Interest related to the PHS-funded research was not disclosed in a timely manner by an Investigator, the interest shall be reviewed within 60 days and a decision shall be made as to whether the Significant Financial Interest constitutes a financial conflict of interest. If the University determines that a financial conflict of interest exists, the University shall implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be taken, to manage the Financial Conflict of Interest.

Financial Conflict of Interest Reports by the University

Prior to the expenditure of any funds under a PHS-funded research award, the University is required to submit to the PHS Awarding Component a financial conflict of interest report ("Report") regarding any Significant Financial Interests related to the PHS-funded research that the University finds to be conflicting and implement a management plan as set forth in this

⁵ Examples of management strategies include but are not limited to: (i) Public disclosure of financial conflicts of interest (*e.g.*, when presenting or publishing the research); (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; (iii) 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; (iv) Modification of the research plan; (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (vi) Reduction or elimination of the financial interest (*e.g.*, sale of an equity interest); or (vii) Severance of relationships that create financial conflicts.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

Appendix C. In addition, during the course of a PHS-funded research project, the University will provide the PHS Awarding Component with a Report, and implement a management plan, within 60 days of identifying any Significant Financial Interest that the University identifies as conflicting subsequent to its initial Report.⁶

For any financial conflict of interest previously reported by the University to PHS, the University shall provide updated Reports annually for the duration of the PHS-funded research project (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Any required Reports shall be submitted to the PHS Awarding Component by the Office of the Vice President for Research.

Retrospective Reviews

If the University identifies a Significant Financial Interest that was not disclosed timely by the Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the University 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 in PHS-funded research is not identified or managed in a timely manner, the University must, within 120 days of the 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 noncompliance, was biased in the design, conduct, or reporting of such research. The University is required to document the review in accordance with PHS requirements.

Based on the results of the retrospective review, the University will, if appropriate, update the previously submitted Reports affected by the review, specifying the actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review determines that the research was biased in its design, conduct or reporting, the University, through the Office of the Vice President for Research, will promptly notify and submit a mitigation report to PHS.

Furthermore, in any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research evaluating the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not managed or reported by the University as required by this Appendix C, the University shall require the Investigator to disclose the

⁶ The University is not required to submit a financial conflict of interest report to PHS if it identifies and eliminates a financial conflict of interest prior to the expenditure of PHS-awarded funds.

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

conflicting interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Maintenance and Disclosure of Records

In accordance with PHS requirements, the University must maintain records relating to all financial disclosures made by Investigators engaged in PHS-funded research, as well as the University's review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a financial conflict of interest) and all actions taken under the Policy and this Appendix C (including any retrospective review, if applicable) for at least three years from submission of the final expenditures report for a grant or cooperative agreement and three years after final payment for a contract, or for such longer periods as prescribed in applicable regulations, and will make such records available in appropriate circumstances for inspection and review upon request by duly authorized agencies.

In addition, the University, through the Office of the Provost and Executive Vice President, will provide a written response to a requestor within five business days of a request for information concerning a Significant Financial Interest held by a Project Director/Principal Investigator and any other person identified by the University to PHS as senior/key personnel if the University has determined that the Significant Financial Interest constitutes a financial conflict of interest in PHS-funded research.

Subgrantees, Contractors, and Collaborators

If the University carries out PHS-funded research through a subrecipient (e.g., subgrantees, contractors, or collaborators), the University, through the Office of the Vice President for Research, will include in its written agreement with the subrecipient a statement as to whether the financial conflicts of interest policy of the University or that of the subrecipient applies to the subrecipient's Investigators.

If the subrecipient's financial conflicts of interest policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations. If the subrecipient cannot make such a certification, the University's policy and this Appendix C will apply to subrecipient Investigators to the extent necessary for compliance with the PHS regulations.

If the subrecipient's financial conflict of interest policy applies, the University, through the Office of the Vice President for Research, will include in the subrecipient agreement time periods for the subrecipient to report all identified financial conflicts of interests to the University. Such time periods must provide the University with sufficient time to review the reports and make timely reports to PHS, as necessary.

If subrecipient Investigators are subject to the University's policy, the subrecipient agreement will specify time periods for the subrecipient to submit subrecipient Investigators' disclosures of Significant Financial Interests to the University so that the University has sufficient time to

POLICY ON CONFLICTS OF INTEREST AND COMMITMENT FOR FACULTY AND INVESTIGATORS

review the disclosures and comply timely with its review, management, and reporting obligations under this Policy.

Notification to PHS

The University, through the Office of the Vice President for Research, will promptly notify the PHS Awarding Component if failure of an Investigator to comply with the Policy or this Appendix C or with a management plan provided for hereunder has biased the design, conduct or reporting of PHS-funded research.

Training

Investigators engaged in PHS-funded research are required to complete training regarding their responsibilities under the Policy and this Appendix C prior to engaging in any PHS-funded research project and at least every four years. Investigators must complete such training immediately if they are new to the University, if the University revises the Policy, Appendix C, or its conflict of interest procedures in a manner that affects the requirements of Investigators, or if the University finds that the Investigator is not in compliance with the Policy or this Appendix C or a management plan adopted thereunder.

Resources

NIH home page:

www.nih.gov

NIH conflict of interest requirements:

<http://www.grants.nih.gov/grants/policy/coi/>

NIH list of conflict of interest information resources available on the Web:

<http://grants1.nih.gov/grants/policy/coi/resources.htm>

Office of the Vice President for Research conflict of interest guidance:

<https://research.gwu.edu/phs-conflicts-interest>