

MEMORANDUM

TO: Gail Eckwright, Faculty Secretary
FROM: M. Duane Nellis, President
DATE: August 22, 2012
SUBJECT: Implementation of Emergency Policy



The attached policy reflects our need to be compliant with federal regulations. As you know, we vetted this policy with Faculty Senate leadership.

Pursuant to FSH 1460 C-3, I enact the attached temporary emergency policy (FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE RESEARCH) to implement revisions to University Policy addressing certain compliance requirements enacted by the US Department of Health and Human Services for research funded through the Public Health Service (PHS). Adoption of this emergency policy is necessary to ensure compliance and to continue significant research grants at the University. The terms of this policy supersede application of FSH 5600 to financial conflicts of interest related to PHS-funded research. FSH 5600 shall continue to govern financial conflicts of interest related to research funded by the National Science Foundation (NSF). This policy is intended to supplement University policies FSH 3170, University Ethics and FSH 6240, Conflicts of Interest or Commitment. The terms of this emergency policy shall remain in effect until such time as this emergency policy lapses pursuant to FSH 1460 C-3 or until a permanent University policy replacing this emergency policy becomes effective.

The US Department of Health and Human Services requires the policy to be adopted and posted no later than Friday August 24, 2012.

cc: Kent Nelson, General Counsel
Jack McIver, Vice President, Research and Economic Development

EMERGENCY POLICY

FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE RESEARCH

PREAMBLE: This emergency policy is intended to comply with substantial changes in Public Health Service regulations (42 C.F.R. 50 and 45 C.F.R. 94). Further information may be obtained from the Office of Research and Economic Development (208-885-4989). [ed. 7-12]

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A. FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE RESEARCH POLICY.

A-1. Purpose. In order to promote objectivity in research and to foster compliance with federal regulations, the University of Idaho requires Investigators seeking research funding (including but not limited to grants, cooperative agreements, and contracts) from a component of the Public Health Service (PHS), to comply with the following policy on the disclosure of significant financial interests and the management and reporting of financial conflicts of interest. This policy is intended to comply with the PHS regulations on *Promoting Objectivity in Research* (42 C.F.R. 50 and 42 C.F.R. 94) and shall supersede application of FSH 5600 to financial conflicts of interest related to PHS-funded research. FSH 5600 shall continue to govern financial conflicts of interest related to research funded by the National Science Foundation (NSF). This policy is intended to supplement University policies FSH 3170, University Ethics and FSH 6240, Conflicts of Interest or Commitment.

A-2. Responsible University Authority: Vice President for Research and Economic Development. The vice president for research and economic development, or designee(s), shall be the university authority who: provides and monitors training of investigators required by federal regulations and/or policy; evaluates all disclosures by investigators made under this policy; determines whether a financial conflict of interest exists; develops and implements a management plan for financial conflicts of interest subject to this policy; performs retrospective review of potential instances of noncompliance with this policy; makes, as required by federal regulation, information on investigator financial conflicts of interest publicly available; and reports, as required by federal regulation, on UI determination of the existence of a financial conflict of interest, UI implementation of management plan for a financial conflict of interest, UI determination of noncompliance, and the results of any retrospective review.

At his or her discretion, the vice president for research and economic development may recommend to the president the establishment of a committee, which shall be regarded as his or her designee under this policy, to fulfill the responsibilities of the vice president established by this policy. Members of such committee shall be nominated by the vice president for research and economic development and appointed by the president.

A-3. Compliance with Financial Conflicts of Interest (FCOI) Requirements of PHS:

a. PHS FCOI Compliance. Any individual who performs, or proposes to perform, research or other activities supported by an awarding component of the Public Health Service or supported by a sponsor that mandates compliance with PHS regulations, shall be subject to the requirements for the disclosure of significant financial interests and management of financial conflicts of interest set forth in Section B. of this policy.

b. Subrecipient/Subcontractor Reliance on UI Policy. UI may permit its subrecipients/subcontractors performing PHS-funded research to rely on this policy, when the subrecipient/subcontractor does not have established policies and procedures that comply with PHS regulations (42 C.F.R. 50 and 42 C.F.R. 94). Such reliance shall only be permitted by written authorization of the vice president for research and economic development, or designee, and when the subrecipient/subcontractor meets at least one of the following criteria:

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- i. subrecipient/subcontractor receives no funding as a prime awardee from PHS awarding component(s);
- ii. subrecipient/subcontractor receives less than \$150,000 annually in subawards/subcontracts for PHS-funded research; or
- iii. subrecipient/subcontractor has fewer than three (3) PHS-funded subawards.

In the event that subrecipient/subcontractor reliance on this policy is authorized, subrecipient/subcontractor, and any subrecipient/subcontractor employees who meet the definition of Investigator (see B-1 below), shall agree, in writing, to comply with this policy; subrecipient/subcontractor shall be subject to all responsibilities and obligations established for Investigators by this policy.

c. Application of More Stringent Standard.

- i. When, because of existing funding and/or proposed research, an individual is subject to both the PHS and NSF FCOI requirements, the PHS requirements set forth in Section B. shall apply.
- ii. On a case by case basis, and when required by a prime awardee with obligations under PHS regulations, UI may agree to more stringent timeframes for disclosure of PHS SFI and reporting related to PHS FCOI. Investigators subject to more stringent timeframes for disclosure of PHS SFI will be notified by UI and will be responsible for disclosure consistent with such timeframes only with respect the award for which UI has agreed to accept disclosure and reporting standard that differ from those set forth in this policy.

d. Other FCOI Compliance Requirements. Any individual who is not performing, or proposing to perform, research or other activities supported by either PHS, or NSF funding governed by FSH 5600, shall comply with the FCOI requirements established by FSH 6240 and/or the external sponsor.

B. POLICY AND PROCEDURE APPLICABLE TO PHS FUNDING

B-1. Definitions.

a. Institutional Responsibilities means, solely for the purposes of conflict of interest procedures applicable to PHS funding described in this Section B, the professional activities of an Investigator on behalf of UI, including but not limited to those activities that fall within the responsibility areas identified in FSH 1565-C and/or those activities Investigators are required to report and certify under APM 45.09.

b. Investigator refers to the project director, principal investigator, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research funded by a component of the Public Health Service (PHS), including, but not limited to the National Institutes of Health (NIH), the Food and Drug Administration (FDA), Center for Medicare and Medicaid Services (CMS) and the Center for Disease Control and Prevention (CDC). (For a list of PHS components [HHS Operating Divisions] please refer to the FAQs maintained by OSP at www.uidaho.edu/osp/financial-conflicts-of-interest/faqs). In addition to UI faculty members, this definition may apply to staff, postdoctoral fellows, graduate students, and (as authorized by the vice president for research and economic development) subrecipient/subcontractor employees, when they assume independent responsibility for portions of the design, conduct, or reporting, of research of an Investigator's proposed or funded project, or when they seek, as permitted by University policy, sponsored research funding subject to this policy.

c. Research is a creative endeavor or a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. 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).

d. Significant Financial Interest (PHS SFI), solely as it applies to conflict of interest procedures applicable to PHS

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funding, means:

i. A financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's spouse, dependent children, and any financially interdependent adult living with Investigator [See e.g. FSH 3705, Expanded Health Benefits]) that reasonably appear to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity within 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;
- 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- With regard to Intellectual Property rights and interests (e.g., patents, copyrights), a *significant financial interest* exists upon receipt of income related to such rights and interests.

ii. Any sponsored travel (i.e., 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) or any reimbursed travel, related to the Investigator's institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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.

iii. The term *significant financial interest* does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by UI to the Investigator if the Investigator is currently employed or otherwise appointed by the UI, including intellectual property rights assigned to UI and agreements to share in royalties related to such rights;
- 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 a 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; or
- income from service on advisory committees or review panels for a 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.

e. Financial Conflict of Interest (PHS FCOI), solely as it applies to conflict of interest procedures applicable to

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PHS funding, means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

f. Business refers to a corporation, partnership, sole proprietorship, trust or foundation, or to any other individual or organization carrying on a business, whether or not operated for profit.

g. Intellectual Property means ideas, inventions, technology, creative expression and embodiments thereof in which a proprietary interest may be claimed without limitation, patents, copyrights, trademarks, know-how, and biological materials. (See also FSH 5300 and 5400)

B-2. Disclosure and Training.

a. Disclosure. Prior to the submission of an application for funding from a component of PHS, each Investigator must disclose to UI all PHS SFI, as defined above, or affirm to UI that he or she has no PHS SFI to disclose. Any new Investigator, who, subsequent to the submission of an application for funding from a component of PHS or during the course of research funded by PHS, plans to participate in the proposed or funded research, must disclose any PHS SFI to OSP or affirm that he or she has no PHS SFI promptly and prior to participation in the proposed or funded research.

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of PHS SFI at least annually during the period of the award. Such disclosure must include any information that was not disclosed initially to UI or in a subsequent disclosure of PHS SFI by the Investigator and must include updated information regarding any previously disclosed PHS SFI.

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of PHS SFI within thirty (30) days of the discovery or acquisition of a new PHS SFI.

All required disclosures shall be submitted to UI through the Office of Sponsored Programs (OSP), using the disclosure mechanism made available by OSP and approved by the vice president for research and economic development.

The Principal Investigator or Project Director, upon consideration of an individual's role and degree of independence in performing the proposed or ongoing PHS-funded research, shall be responsible for identifying to OSP all individuals involved in the research who meet the definition of Investigator.

b. Training. Investigators shall complete training on the UI financial conflict of interest policy, Investigator responsibilities with respect to disclosure of SFI, and PHS regulations on *Promoting Objectivity in Research* prior to engaging in any PHS-funded research, at least every four years thereafter, and immediately when any of the following circumstances apply:

- UI revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- an Investigator is new to UI; or
- UI finds that an Investigator is not in compliance with this conflict of interest in research policy, or a management plan developed and implemented pursuant to this policy.

B-3. Review of PHS SFI Disclosures and Determination of PHS FCOI.

The vice president for research and economic development, or designee(s), shall timely review, as required by PHS regulations, all disclosed PHS SFI for funded research projects or for those projects for which UI has been notified by the agency that the application is to be funded, to determine whether the disclosed PHS SFI is related to the PHS-funded research of the disclosing Investigator and, if so, whether the disclosed PHS SFI rises to the level of a PHS FCOI,

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because it directly and significantly affects the design, conduct, or reporting of the PHS-funded research. The vice president for research and economic development may, at his or her discretion, seek additional information from an Investigator who has made a disclosure of PHS SFI.

B-4. Management of PHS FCOI.

If a disclosed PHS SFI is determined to be PHS FCOI, the vice president for research and economic development shall determine the conditions or restrictions to be imposed and implemented as part of a formal management plan in order to manage or eliminate the conflict. Examples of conditions or restrictions that might be imposed 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.

The vice president for research and economic development shall communicate this determination, and the means that he or she has identified for eliminating or managing the PHS FCOI, to the individual Investigator, the relevant Principal Investigator or Project Director (if applicable), the appropriate unit administrator and/or dean, the UI Committee on Ethical Guidance and Oversight, and, as necessary, the PHS awarding component.

Information regarding the existence and management of PHS FCOI may also be communicated to any University committees responsible for research compliance (including but not limited to the Institutional Review Board, the Institutional Animal Care and Use Committee, and the Institutional Biosafety Committee). Such committees may, consistent with their responsibilities, establish additional requirements with respect to any identified FCOI or may contribute, in satisfaction of their responsibilities related to financial conflicts of interest, contribute to management plans established under this policy.

No expenditures on PHS awards will be permitted until the Investigator has complied with the disclosure and training requirements of this policy and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of PHS FCOI.

B-4. Access to Information Related to PHS FCOI.

a. Public Access. Prior to expenditure of any funds under a PHS-funded research project, UI shall ensure public accessibility, via a publicly accessible web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

- i. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart; and
- ii. The Institution determines that the significant financial interest is related to the PHS-funded research; and
- iii. The Institution determines that the significant financial interest is a financial conflict of interest.

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Information regarding any PHS FCOI made publicly available by UI, whether by web site or written response, shall include, at a minimum:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which each PHS SFI is held;
- The nature of each PHS SFI; and
- The approximate dollar value of each PHS SFI, in the following ranges:
 - \$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 the interest is one for which a value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

b. Reporting to PHS Awarding Component and PHS Awarding Component Access to Information Related to PHS FCOI.

Prior to the expenditure of any funds under a PHS-funded research project, UI shall provide to the PHS awarding component a report, compliant with PHS regulations, regarding any Investigator's significant financial interest found by UI to be conflicting (i.e. PHS FCOI) and the corresponding plan established and implemented by UI to manage the PHS FCOI. With regard to an ongoing PHS-funded research project (including any extension with or without funds), UI shall provide for any PHS FCOI previously reported to a PHS awarding component an annual report that addresses the status of the previously reported PHS FCOI and any changes in the corresponding management plan.

For any PHS SFI that is identified as conflicting subsequent to an initial conflict report made by UI to a PHS awarding component during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), UI will provide to the PHS awarding component, within sixty days, an FCOI report regarding the PHS FCOI and will ensure that a management plan has been established and implemented for the identified PHS FCOI.

For any failure to comply with this policy, as described in Section B-5 below, UI shall provide the PHS awarding component a report that describes any retrospective review performed and any mitigation plan established and implemented to eliminate or mitigate bias in the research related to a failure to comply with this policy.

B-5. Failure to Comply with Policy Applicable to PHS Funding and Sanctions.

a. When PHS SFI is not timely disclosed (within thirty [30] days of discovering or acquiring a PHS SFI) by an Investigator, an Investigator fails to comply with a management plan established by UI, or, for whatever reason, PHS SFI was not previously reviewed or, if determined to be PHS FCOI, managed by UI, UI shall within one hundred and twenty (120) days of UI'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. If bias is found, UI shall develop and implement a plan to eliminate or mitigate the effect of the bias and shall submit a mitigation report, as required by regulation, to the PHS awarding component.

b. Failure to fully and timely disclose all PHS SFI (including but not limited to failure to submit a PHS SFI disclosure report, required updates to such disclosures, or submission of an incomplete, erroneous, or misleading initial, updated,

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or annual disclosure of PHS SFI), failure to comply with the conditions of a management or mitigation plan, or violations of this policy by an Investigator shall be considered a violation of university policy and regulations and shall result in a formal inquiry and an investigation by the vice president for research and economic development, or designee(s). The vice president for research and economic development, or designee(s), may recommend sanctions such as, but not limited to, the following:

- a. disciplinary action up to and including suspension and dismissal;
- b. requiring repayment of all financial benefits resulting from such violation;
- c. freezing research funds or accounts;
- d. rescinding contracts entered in violation of this policy, federal law, or state law;
- e. bringing legal action to recover the amount of financial benefit received by an employee as a result of the employee's violation of this policy;
- f. disclosing FCOI in each public presentation of the results of research;
- g. requiring an addendum related to FCOI for inclusion in previous publications or presentations.

Formal inquiry and investigation by the vice president for research and economic development, including any recommendations pursuant to such inquiry and investigation, shall not limit, delay, or supersede any actions undertaken by UI, including but not limited to the establishment and implementation of PHS FCOI management or mitigation plans and the reporting of noncompliance, deemed necessary by UI to ensure compliance with this policy and applicable regulations.

B-6. RECORD RETENTION. UI, through OSP, shall maintain all records relating to all Investigator disclosures of financial interests and UI's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under this policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS awarding component or, as applicable, for the retention period identified by other applicable federal regulations (including but not limited to 45 CFR 74.53(b) and 92.42(b)).

C. REMEDIES CUMULATIVE. The remedies provided and referenced herein are cumulative and shall be deemed to include any other remedies required or provided by applicable state or federal law.

D. OTHER LAW. This policy shall be deemed to include all requirements relating to conflicts of interest to which UI is subject under state or federal law. To the extent that requirements and standards under applicable state or federal law are more stringent than those identified in this policy, the more stringent requirements and standards shall take precedence.