

SOUTH DAKOTA BOARD OF REGENTS

Policy Manual

SUBJECT: Public Health Service Investigator Financial Disclosure

NUMBER: 4:32:1

On August 25, 2011, the United States Department of Health and Human Services published new regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 75 Fed. Reg. 53256. These rules incorporate deliberate changes from practices that were first put in place in 1995 to regulate conflicts of interest for all investigators receiving research grant support from federal agencies.

The new rules apply only to research funding provided through a Public Health Service component or program, including the National Institutes of Health or the Small Business Innovation Research Program, without regard to whether the funding is provided pursuant to a contract or a grant or cooperative agreement.

The regulations published on August 25, 2011, seek to enhance regulatory compliance and management of conflicts by increasing the range of circumstances in which a direct or indirect financial interest is subject to disclosure requirements and by shifting from the researchers themselves to the grantee institutions primary responsibility for identifying significant investigator financial interests related to the conduct of research. The regulations make recipient institutions responsible for managing identified conflicts, for providing public disclosure of information about financial interests that the institutions deem to present significant financial interests and for filing reports with the Department of Health and Human Services.

The present policy implements the August 25, 2011 regulations and complements Board Policy No. 4:32, which remains in effect for research grants funded by other federal agencies.

1. Definitions

- A. “Designated officer” means the person designated by the institutional chief executive officer to manage this policy on behalf of the institution, including solicitation and review of disclosures from each investigator, responding to public requests for information about significant conflicts of interests, filing financial conflict of interest reports with the Public Health Service, supervising training and recordkeeping and otherwise exercising or overseeing the immediate administration of the policy. The term “designated officer” includes any officer exercising authority delegated by the designated officer.

- B. “Disclosure,” and its cognates, means disclosure of any significant financial interests to the designated officer of the institution.
- C. “Financial conflict of interest” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research funded by the Public Health Service.
- D. “Financial conflict of interest report,” means an Institution's report of a financial conflict of interest to the Public Health Service under 42 CFR part 50, subpart F, or 45 CFR part 94.
- E. “Financial interest” means anything of monetary value, whether or not the value is readily ascertainable.
- F. “Institution” means an institution of higher education governed by the Board.
- G. “Institution of higher education” means an institution of higher education as defined at 20 U.S.C. § 1001(a).
- H. “Institutional responsibilities” means an investigator's professional responsibilities on behalf of the institution, and as defined by the institution in its policy on financial conflicts of interest, which may include for example: 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" 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 the Public Health Service, or proposed for such funding, which may include, for example, collaborators or consultants.
- J. “Manage” means 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 objective.
- K. “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). For purposes of this policy, the term includes any such activity for which research funding is available from the Public Health Service through a contract or through a grant or cooperative agreement, whether authorized under the Public Health Service Act or other statutory authority. Grants or cooperative agreements include, by way of illustration but not limitation, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, or research resources awards.

L. The terms “senior personnel” or “key personnel” include those investigators and any other person identified as senior or key personnel by the institution in the grant application, progress report, or any other report the Public Health Service under 42 CFR part 50, subpart F, or 45 CFR part 94, and the term also includes key personnel specified in contract to provide property or services for the direct benefit or use of the Public Health Services as essential to work performance promised under the contract.

M. "Significant financial interest" means:

- 1) A financial interest consisting of one or more of the following interests of an investigator (and those of the investigator's spouse 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2) Travel related to an investigator’s institutional responsibilities, unless the travel 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) The term significant financial interest does not include the following types of financial interests:
 - a. salary, royalties, or other remuneration paid by the Institution to the investigator if the investigator is currently employed or otherwise

appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;

- b. any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for-profit organization;
- c. 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;
- d. 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;
- e. or 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.

2. Each Institution will:

- A. Inform each investigator of this policy, the investigator's responsibilities regarding disclosure of significant financial interests, and the Public Health Service Regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94, and require each investigator to complete training regarding the same prior to engaging in research related to any Public Health Services funded grant and at least every four years after the initial training, and immediately when any of the following circumstances apply:
 - 1) The Board revises this policy or the institution revises implementing procedures in any manner that affects the requirements of investigators;
 - 2) An investigator is new to the institution; or
 - 3) The institution finds that an investigator is not in compliance with the institution's financial conflict of interest policy or management plan.
- B. If the Institution carries out the Public Health Services funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) will take reasonable steps to ensure that any subrecipient investigator complies with the Public Health Service Regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94 by:

- 1) Incorporating as part of a written agreement with the subrecipient terms that establish whether this policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's investigators.
 - a. 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 the Public Health Service Regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94.
 - i. If the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement will require the subrecipient to report all identified financial conflicts of interest to the institution with sufficient advance time to enable the institution to provide timely financial conflict of interest reports to the Public Health Service when required under the regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94.
 - b. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient investigators are subject to this policy for disclosing significant financial interests that are directly related to the subrecipient's work for the institution.
 - i. If the subrecipient's investigators must comply with this policy, the agreement will require the subrecipient to report all identified significant financial conflicts of interest to the institution with sufficient advance time to enable the institution to comply timely with its review, management, and reporting obligations under the regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94.
 - 2) Assign responsibilities to the designated officer to establish and to publish through a website established for this purpose administrative procedures to assure compliance with the publication, training, enforcement, recordkeeping and reporting requirements set forth in Public Health Service Regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94.
 - 3) Implement internal controls to prevent the release of Public Health Service research funding until the designated individual confirms compliance with the requirements of §§ 3 through 6 of this policy.
3. Prior to the time that the institution submits a proposal for Public Health Service funded research, all investigators and other senior or key personnel must disclose to the designated officer all significant financial interests (including those of their spouses and dependent children) that may reasonably relate to any of the institutional responsibilities (whether or not

these responsibilities involve Public Health Service funded research) of the investigators or senior or key personnel.

- A. Each investigator and all senior or key personnel will update the disclosure annually at the same time that disclosures are filed under Board Policy No. 4:35.
 - B. Each investigator and all senior or key personnel will update the disclosure within thirty days of discovering or acquiring a new significant financial interest.
4. The designated officer will review the significant financial disclosures to determine whether a financial conflict of interest exists to determine whether the interest is related to Public Health Service funded research.
- A. An investigator's significant financial interest is related to Public Health Service funded research when the designated officer reasonably determines that the significant financial interest:
 - 1) could be affected by the Public Health Services funded research; or
 - 2) is in an entity whose financial interest could be affected by the research.

When assessing the relatedness of a significant financial interest to Public Health Service funded research, the designated officer may consult with persons who are familiar with the scientific disciplines involved in the research and who have entered into nondisclosure agreements that cover the information reviewed in the course of the assessment. The designated officer may also consult with the investigator whose significant financial interest is being reviewed.

5. If the designated officer reasonably determines that significant financial interest related to Public Health Service funded research could directly and significantly affect the design, conduct or reporting of the research, the designated officer will embargo the Public Health Service funds pending the development and implementation of a management plan specifying the actions that have been, and that will be, taken to safeguard the objectivity of the research by eliminating, reducing or managing the financial conflict of interest.
- A. The designated officer will consult with the investigator's immediate supervisor when developing the management plan. Where useful, the designated officer may also consult with persons who are familiar with the scientific disciplines involved in the research and who have entered into nondisclosure agreements that cover the information reviewed in the course of the assessment.
 - 1) Each management plan will contain, at minimum, the following elements:
 - a. An explanation of the role and principal duties of the conflicted investigator in the research project;

- b. An explanation of each condition or restriction included in the management plan;
 - c. An explanation of how the management plan will safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan; and
 - e. An explanation of how the management plan will be monitored to ensure investigator compliance.
 - 2) The designated officer will provide the investigator with a draft of the management plan, and, before finalizing the plan, will consider any comments that the investigator may tender.
- B. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - 1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - 2) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 3) 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;
 - 4) Modification of the research plan;
 - 5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 6) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - 7) Severance of relationships that create financial conflicts.
- C. Each management plan will require the investigator,
 - 1) to agree to comply with the conditions and restrictions management plan,
 - 2) to provide the designated officer access to such places, equipment or records that may assist the designated individual to confirm compliance with the management plan,

- 3) to file with the designated officer a report documenting those actions taken to comply with the plan conditions or restrictions,
 - 4) to meet annually with the designated officer to review the plan,
 - 5) to notify the designated officer within thirty days of any event that may involve a material change in the circumstances addressed by the management plan, including the acquisition or discovery of a new significant financial interest or the divestment of the interest that presented the financial conflict of interest addressed in the management plan,
 - 6) to cooperate fully with the designated officer in managing the financial conflict of interest and in complying with the requirements of this policy and the regulations published at 42 CFR part 50, subpart F, or 45 CFR part 94, and
 - 7) to acknowledge that violation of the management plan may result in discipline, which may include termination.
6. The finalized management plan will be reduced to writing, and the investigator will only be authorized to participate in the Public Health Service funded research after the investigator has signed the written management plan.
- A. Where the financial conflict of interest involves one or more senior or key personnel, no Public Health Service funds will be released for the research until all such participants in the research have executed management plans, have divested themselves of the interest that constituted a financial conflict of interest or have been replaced.
 - B. Once the requirements of this section have been satisfied, the designated officer will file required reports with the Public Health Service.
 - 1) In the event that institution learns of a significant financial interest that, under whatever circumstances, was either not disclosed or not reviewed when required under this policy, the designated officer will initiate an appropriate review to determine whether the significant financial interest is related to the research and whether the relationships is so direct and significant that it might reasonably be determined to affect the design, conduct, or reporting of the Public Health Service funded research and thereby constitute a financial conflict of interest. The investigator, together with any senior or key personnel, will cooperate fully with the designated individual in furtherance of the review, irrespective of the circumstances that gave rise to the need for the review.
 - 2) If the designated officer determines that the interest constituted a financial conflict of interest, the designated officer will conduct a retrospective review of the research protocols, the use of data and the interpretation of results for

evidence that the research was conducted in a manner that furthered the significant financial interest.

- 3) In all cases involving a financial conflict of interest, the designated officer will develop an appropriate management plan, initiate any necessary corrective action and otherwise act to mitigate the consequences of the failure timely to disclose or to review the significant financial interest.
 - 4) The designated officer will also file such reports and take such actions as may be required to comply with 42 CFR part 50, subpart F, or 45 CFR part 94.
 - 5) The designated officer will supervise the process for providing public access to information about financial conflicts of interest held by senior or key personnel and pertinent to their activities in conducting Public Health Service funded research.
- A. The institution will inform the public, through a website maintained as part of the website that describes its research programs, how any person may obtain information about such financial conflicts of interest.
- 1) Only written request for disclosure will be honored.
 - 2) The website will identify the institutional officer or employee responsible for responding to such requests and will inform visitors where they should direct their requests.
 - a. Three forms of correspondence may be permitted:
 - i. The website may support the online submission of an inquiry;
 - ii. The website may provide an address to permit the submission of an inquiry using electronic mail; or
 - iii. The website will provide an address for submission of written requests through the United States postal service.
 - 3) The institution will respond to the inquiry by sending a written report to the electronic or physical address specified by the requester.
 - 4) The institutional officer or employee charged with responding to such requests will record the date upon which a request is received and will send a response within the ten working days following the date of receipt.
- B. The following information shall be provided in response to such requests:
- 1) the Investigator's name;

- 2) the Investigator's title and role with respect to the research project;
 - 3) the name of the entity in which the significant financial interest is held;
 - 4) the nature of the significant financial interest; and
 - 5) the approximate dollar value of the significant financial interest (to be reported using dollar 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 whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- C. The information compiled for purposes of subparagraph B of this section will remain available, for responses to written requests for at least three years from the date that the information was most recently updated.

SOURCE: BOR, August 2012.