

SOUTH DAKOTA BOARD OF REGENTS

Policy Manual

SUBJECT: Investigator Financial Disclosure

NUMBER: 4:32

1. Definitions

- A. The term "investigator" means the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by Federal agencies requiring disclosure of investigator financial interests.
- B. The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (*e.g.*, consulting fees or honoraria); equity interests (*e.g.*, stocks, stock options or other ownership interests); and intellectual property rights (*e.g.*, patents, copyrights and royalties from such rights).
1. The term "significant financial interest" does not include:
- a. salary, royalties or other remuneration from the institution, or any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
 - b. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - c. income from service on advisory committees or review panels for public or nonprofit entities; or
 - d. financial interests in business enterprises or entities if the value of such interests, when aggregated with interests owned by the investigator's spouse or dependent children, do not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a 5 percent ownership interest for any single entity; or
 - e. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve month period.

2. Prior to the time that a proposal is submitted to Federal agencies that require disclosure of investigator financial interests, all investigators must disclose to the chief executive officer of the employing institution, or to that person's designee, all significant financial interests of the investigator (including those of the investigator's spouse and dependent children)
 - A. that would reasonably appear to be significantly affected by the research or educational activities funded or proposed for funding by Federal agencies that require disclosure of investigator financial interests; or
 - B. in entities whose financial interests would reasonably appear to be significantly affected by such activities.

A financial disclosure must be updated during the pendency of the award application and during the period of the award, either annually on July 1, or as new reportable significant financial interests are obtained.

3. The chief executive officer of the employing institution, or that person's designee, shall review financial disclosures and determine whether an actual or potential conflict of interest exists.
 - A. If the chief executive officer or that person's designee determines that an actual or potential conflict of interest exists, the chief executive officer shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest.
 1. Although a designee may recommend conditions or restrictions to the chief executive officer, the chief executive officer shall be responsible to approve such conditions or restrictions.
 - a. Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate actual or potential conflicts of interest include, but are not limited to:
 - i. monitoring of research by independent reviewers;
 - ii. modification of the research plan;
 - iii. disqualification from participation in the portion of the research funded by Federal agencies that require disclosure of investigator financial interests that would be affected by the significant financial interests;
 - iv. divestiture of significant financial interests; or
 - v. severance of relationships that create actual or potential conflicts.

- B. An actual or potential conflict of interest exists when the reviewer(s) reasonably determine that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research or educational activities funded or proposed for funding by Federal agencies that require disclosure of investigator financial interests.
4. If the chief executive officer determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the chief executive officer may allow the research to go forward without imposing such conditions or restrictions.
 - A. The chief executive officer may not delegate the responsibility to make the determination that imposition of conditions or restrictions would be ineffective or inequitable.
 5. All financial disclosures made, together with records of actions taken to resolve actual or potential conflicts of interest, shall be treated as confidential material to be held in the faculty unit member's personnel file during the pendency of the grant application and any subsequent award period and for three years following the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.
 - A. The rights of confidentiality are subject to the obligation of the institution to make necessary disclosures upon proper demand by the Federal agencies that require disclosure of investigator financial interests or in the context of any governmental audit of its sponsored research programs or activities.
 - B. The rights of confidentiality shall be deemed waived by investigators, their spouses or children, or the successors in interest of any of these, where the disclosure of such information is necessary to defend the interests of the institution against grievances or other legal proceedings initiated by or involving the investigators or persons whose interests were disclosed pursuant to this policy, or the successors in interest of any such persons.
 6. Faculty unit members may initiate a grievance to challenge a determination that proposed research poses an actual or potential conflict of interest.
 7. The determination of appropriate conditions or restrictions to counter actual or potential conflicts of interest shall rest solely with the institutional chief executive officer and may not be subject to challenge through the grievance proceedings, unless the grievant alleges that the conditions or restrictions were imposed for purposes proscribed under the agreement.
 8. Investigators who fail to disclose significant financial interests or who fail to comply with duly approved conditions or restrictions on the treatment of such interests shall be subject to discipline. Discipline may include termination.

9. The institutional chief executive officer shall inform the Federal agencies that require disclosure of investigator financial interests if the institution finds that it is unable to satisfactorily manage an actual or potential conflict of interest.

SOURCE: BOR, Oct. 1995