



FINANCIAL CONFLICTS OF INTEREST (FCOI) POLICY

*FOR NIH GRANT INVESTIGATORS

Preamble

The Society of Behavioral Medicine (SBM) is a multidisciplinary organization of clinicians, educators, and scientists dedicated to promoting the study of the interactions of behavior with biology and the environment, and then applying that knowledge to improve the health and well-being of individuals, families, communities, and populations. The vision of SBM is to pursue better health through behavior change. Health is defined by the World Health Organization as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity.

Policies/Processes

Per NIH requirements, SBM complies with all requirements of [42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" \(FCOI Regulation\)](#), as implemented in the 2011 Final Rule for grants and cooperative agreements.

SBM provides this Financial Conflicts of Interest (FCOI) policy to all potential investigators and requires disclosure form completion from all investigators, as a way to comply with NIH requirements and ensure investigators are informed of our policy, their disclosure responsibilities, and the federal regulation. Disclosure form completion is required: (1) No later than at the time of application for PHS-funded research; (2) At least annually during the period of the award; and (3) Within 30 days of discovering or acquiring a new significant financial interest (SFI).

The SBM Executive Director shall review disclosure forms, determine if relevant SFIs and FCOIs exist, and implement and monitor management plans for actual SFIs and FCOIs; these steps shall be guided by the SBM Board of Directors' conflict disclosure guidelines.

The Executive Director shall send any required FCOI reports to NIH, according to the regulation. This includes but is not limited to annual reports, mitigation reports, and any findings of bias. Further, when requested, the Executive Director will promptly make information available to the NIH/HHS relating to any investigator disclosure of financial interests and SBM's review of, and response to, such disclosure, whether or not the disclosure resulted in SBM's determination of an FCOI.

The SBM National Office shall maintain all FCOI-related records that meet or exceed the regulatory requirements: For at least 3 years from the date the final expenditures report is submitted to the PHS (NIH); and From other dates specified in 45 CFR 75.361, where applicable.

Investigator non-compliance with this policy and disclosure requirements may result in removal of the investigator from the relevant grant or project. After a determination of non-compliance, the SBM Executive Committee shall complete and document a retrospective review within 120 days. SBM does not apply for or receive grants for clinical research; as such, additional DHHS non-compliance reporting requirements do not apply.

SBM shall meet all subrecipient FCOI requirements, as applicable.

This policy is publicly posted on the SBM website. SBM will also publicly post any information concerning identified FCOIs, in accordance with the regulation.

Definitions

An "**investigator**" is someone:

- defined as the PD/PI 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 such funding;
- and may include, for example, collaborators or consultants.

A "**conflict of interest**" arises when an Investigator who is required to exercise judgment and make decisions on behalf of SBM also has financial or other business relationships that are likely to or directly compromise his/her ability to make an impartial judgment. An apparent conflict of interest is present if there is a potential for the financial or other business relationships of a person to be at odds with the person's obligation to SBM and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the person's ability to act in SBM's best interests.

A "**financial conflict of interest**" exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

SBM defines financial interests as direct financial holdings, (exclusive of mutual funds) valued at \$10,000.00 or greater in any company with which SBM could conceivably transact or is transacting business including, but not limited to: consulting firms; companies that sponsor, have sponsored, or could be invited to sponsor SBM's annual meeting or other events; and publishing firms. Disclosure is required if you, your spouse, partner, minor children or someone with whom you directly share income has financial holdings.

Other Possible Financial Conflicts

- Paid consultancy or expert testimony within the past two years
- Research funding (identify subject matter and funding organization, if permissible)
- Honoraria, stipends, or gifts exceeding \$100 in value per engagement directly received from an entity
- Royalties

Additionally, the 2011 revised regulation defines a "**significant financial interest**" as follows:

- (1) A 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:
 - (i) 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;
 - (ii) 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

- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (2) Investigators also must disclose the occurrence of any reimbursed or 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), related to their 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) 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 with the PHS-funded research.
- (3) The term significant financial interest does not include the following types of financial interests: 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; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

SBM defines "**business relationships**" between two persons to include any of the following:

- (1) One person is employed by the other in a sole proprietorship or by an organization with which the other is associated as a trustee, director, officer, key employee, or greater-than-35% owner.
- (2) One person is transacting business with the other (other than in the ordinary course of either party's business on the same terms as are generally offered to the public), directly or indirectly, in one or more contracts of sale, lease, license, loan, performance of services, or other transaction involving transfers of cash or property valued in excess of \$10,000 in the aggregate during the organization's tax year. Indirect transactions are transactions with an organization with which the one person is associated as a trustee, director, officer, key employee, or greater-than-35% owner. Such transactions do not include charitable contributions to tax-exempt organizations.
- (3) The two persons are each a director, trustee, officer, or greater than 10% owner in the same business or investment conducts investment entity (but not in the same tax-exempt organization).

Ownership is measured by stock ownership (either voting power or value) of a corporation, profits or capital interest in a partnership or limited liability company, membership interest in a nonprofit organization, or beneficial interest in a trust. Ownership includes indirect ownership (for example, ownership in an entity that has ownership in the entity in question); there may be ownership through multiple tiers of entities.

Privileged relationship exception: A “business relationship” does not include a relationship between an attorney and client, a medical professional (including psychologist) and patient, or a priest/clergy and penitent/communicant.

END OF POLICY



CONFLICTS OF INTEREST FORM

Instructions: Please indicate any actual or apparent financial or other business conflicts of interest you (or your spouse, partner, minor children or someone with whom income is directly shared) have. Disclosures must be made when an actual or apparent conflict exists that directly relates to the relationship you have with SBM (e.g., grant investigator) and that has the potential to affect your judgment or impartiality with regard to your participation in decision-making activities.

No conflicts to declare.

Conflicts to declare:

	Entity/Person	Nature of Conflict
<i>Financial</i>		
<i>Business Relationship</i>		

Acknowledgment: By completing this form and signing below, I verify that I have read the SBM Financial Conflicts of Interest Policy and understand and support its intent. Further, I agree to abide by all of its provisions and verify that the information reported above is true and accurate. I also agree to update the information disclosed whenever necessary to report new conflicts.

Training Acknowledgement: By completing this form and signing below, I verify that I will complete FCOI training via my institution as follows: (1) Prior to engaging in research related to any PHS-funded grant; (2) At least every 4 years; and (3) Immediately, if: Institution revises its FCOI policy that affects requirements of Investigators; An Investigator is new to an Institution; or An Investigator is not in compliance with the policy or management plan.

Printed Name _____

Signature _____

**Please sign and return form by fax, mail, or email to the
SBM National Office at the following address:**

Society of Behavioral Medicine
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Fax: 414-276-3349 | Email: lbullock@sbm.org