Society for Birth Defects Research and Prevention
Financial Conflict of Interest (FCOI) Policy

Effective January 1, 2021, the Society for Birth Defects Research and Prevention (BDRP) policy requires that each investigator, subrecipients, subgrantees, and collaborators affiliated with BDRP, by the National Institutes of Health (NIH) or any other applicable grant or contract, be in compliance with the FCOI standard 42 CFR Part 50, Subpart F for Public Health Service (PHS) grants and cooperative agreements (and 45 CFR Part 94 for contracts). In addition, this legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards.

The following are key term definitions and BDRP's policy guidance for principal or program investigators, subrecipients, subgrantees, and collaborators affiliated with BDRP. This policy and all BDRP conflict of interest guidance are also available in the BDRP's Code of Ethics and Conflict of Interest Policy.

Financial Conflict of Interest
A Financial Conflict of Interest (FCOI) exists when the BDRP'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.

Investigator
An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by PHS.

Training and Reporting Requirement
Those associated with grants to BDRP are required to complete training related to Financial Conflict of Interest. If any conflicts of interest are found or known, they must be disclosed. The training must be updated no less than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site and the definitions below are based on that information.

Significant Financial Interest
A Significant Financial Interest (SFI) is defined by the regulations 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:
    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. 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."

The Society for Birth Defects Research and Prevention:

- Shall promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports.
- Agrees to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, promptly, upon request.
- Shall fully comply with the regulation's requirements.

Training Requirements

BDRP will, at the time of initiation of a grant submission, inform each Investigator of BDRP's policies, the Investigator's disclosure responsibilities, and the Federal regulation. By the beginning of each funded grant, the Investigator will complete FCOI training, and this training will be repeated at least every four years. The training will be required immediately if BDRP revises its FCOI policy that affects requirements of the Investigators, the Investigator is new to a BDRP grant, or if an Investigator is not in compliance with the policy or management plan.

Disclosure, Review, and Monitoring Requirements
No later than the time of application for PHS-funded research, each Investigator will disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI: 42 CFR 50.603 and 42 CFR 50.604(e)(1)-(3) using the form required by BDRP. In addition, the Investigator will disclose SFIs annually at the initiation of funding for the next year and within thirty days of discovering or acquiring a new SFI.

The BDRP Signing Official (SO) will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's responsibilities relative to BDRP grants prior to submission of PHS-related grants, when a new Investigator joins the project, or if an existing Investigator reports a new FCOI. The SO will provide adequate guidelines consistent with the regulation for the designated institutional official(s) to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI.

The SO will review all declarations. If no FCOIs are declared, the forms will be filed for retention for at least three years. Should the SO note declarations that may represent a FCOI, the BDRP President or their designated representative will review these to determine if the potential FCOI relates to PHS-funded research and if a FCOI exists (a SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research). Should such a conflict be confirmed, the FCOI report will be submitted through the eRA Commons module prior to spending any funds. The BDRP representative will develop and implement management plans as needed for the specific FCOIs. Management could include, but not be limited to, shifting responsibilities on the grant to avoid the FCOI. Within sixty days of identification of an SFI that was not disclosed in a timely manner by an Investigator or not previously reviewed by BDRP, the SO and BDRP President or representative will review the SFI and decide of the existence of a FCOI and the appropriate management plan, if so.

The SO, in consultation with the President, will manage FCOIs consistent with the regulation.

In any case in which the DHHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by BDRP as required by the regulation, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations.

Reporting Requirements to NIH
The SO will send the initial, annual (i.e., ongoing), and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for BDRP and its subrecipients, if applicable, as required by the regulation:

- Prior to the expenditure of funds
- Within sixty days of identification of an Investigator who is newly participating in the project
- Within 60 days for new, or newly identified, FCOIs for existing Investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report, if appropriate.

The SO will notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research and will submit the required Mitigation Report in accordance with the regulation. The SO will also promptly notify NIH if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. BDRP will promptly take corrective action for noncompliance with the BDRP policy or the management plan.

Maintenance of Records
All FCOI-related records will be maintained for at least three years from the date the final expenditures report is submitted to PHS (NIH) or from other dates as specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

Enforcement Mechanisms and Remedies and Noncompliance
BDRP will enforce this policy through appropriate actions, which may include employee sanctions, changing key personnel, or other administrative actions to ensure Investigator compliance.
BDRP requires that retrospective reviews will be completed and documented within 120 days of the Institution's determination of noncompliance for SFIs whenever an FCOI is not identified or managed in a timely manner. Reviews will be documented consistent with the regulation.

In any case in which the DHHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, BDRP shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Requirements
In cases where an BDRP grant has subrecipients, BDRP will require a written certification confirming that the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the Subrecipient, and that the subrecipient policy complies with the regulation. The subrecipient will report identified FCOIs for its Investigators in a time frame that allows BDRP, the awardee Institution, to report identified FCOIs to the NIH as required by the regulation.

Public Accessibility Requirements
The BDRP FCOI policy is publicly accessible on the BDRP website. Should the policy not be available on the website, and only in those cases, BDRP will make the FCOI policy available within five business days of a request.

Information concerning identified FCOIs held by senior/key personnel (as defined by the regulation) will be publicly available prior to expenditure of funds. The information will be made available within five business days of a written request to the SO. This information will include the minimum elements as provided in the regulation. The information available to the public will be updated at least annually or within sixty days of a newly identified FCOI. The information will remain available for three years from the date the information was most recently updated.