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## Financial Conflict of Interest Policy for the Society for the Study of Reproduction

**NIH Principal Investigator:** Troy Ott, PhD

Email: [tlo12@psu.edu](mailto:tlo12@psu.edu)

### PURPOSE

The purpose of this policy is to set forth the standards and procedures for reporting and reviewing potential institutional conflicts of interest and to provide a process by which the Society for the Study of Reproduction (SSR) will manage, reduce, or eliminate those conflicts. As a steward of public funds, SSR strives to ensure that its research, teaching, outreach, business transactions and other activities are not inappropriately affected by, nor appear to be inappropriately affected by, the financial or business interests of the society. While it is widely recognized that society-industry relationships are essential in advancing scientific knowledge and enabling the commercial development of discoveries to the benefit of the public, SSR will not allow its financial or business interests, or the financial or business interests of SSR Officials, to compromise the integrity of the society's primary mission or to inappropriately influence decisions regarding society activities.

### POLICY

Financial or business interests of SSR or of SSR Official Leaders must be identified, disclosed and reviewed for potential institutional conflicts of interest according to the processes set forth below. Institutional financial interests can be created by gifts, payments, royalty income, equity and other financial benefits from or interests in for-profit entities. Institutional financial interests can also be created by financial and fiduciary interests of Society Officials. When an institutional conflict of interest is identified, a management plan will be implemented to manage, reduce, or eliminate the institutional conflict. SSR's Executive Council shall review and evaluate the financial or business interests of the Society or of Society Officials to identify potential institutional conflicts of interest; shall create, in collaboration with the appropriate SSR officials, management plans to manage, reduce or eliminate institutional conflicts of interest that are identified; and shall provide oversight to the implementation and monitoring of management plans created. The SSR Executive Council may also implement additional administrative procedures associated with this policy to assist in its responsibilities outlined here. SSR will strive to manage or eliminate each institutional conflict of interest identified before any contract, sponsored project, dedicated gift, or transaction is executed; any contractual relationship is initiated; or any action is taken that might be inappropriately affected or appear to be inappropriately affected by the institutional conflict of interest. Potential conflicts of interest that involve members of the SSR Board of Directors are covered by the conflict-of-interest provisions applicable to the Board in the SSR Bylaws.

Each year, any investigator who represents SSR on any grant program must acknowledge they have read and understood the SSR Financial Conflict of Interest Policy. They must also disclose via the electronic system all significant financial interests (SFIs) that are relevant to

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the Society's research responsibilities within 30 days after the individual becomes aware of new SFI or after a financial conflict of interest has been eliminated. Investigators are required to complete the annual disclosure form even if they have no financial interest to report.

The Significant Financial Interest (SFI) Disclosure Form will contain the following information:

- Investigator's name
- Entity name in which the Investigator (and spouse and dependent children) has an SFI
- Disclosure requirement that is consistent with the institution's definition of SFI
- Disclosure of financial interests in the 12 months preceding the disclosure and value of equity interest as of the date of disclosure
- Provide for disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests (Note: Institutions may impose a \$5,000 threshold for IP rights and interests as described in the [Final Rule](#) on page 53265).
- Provide for the disclosure of reimbursed or sponsored travel that includes at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- Ensure the SFI definition includes the "U.S.C. Code 20 U.S.C. 1001(a)" which refers to "domestic" institutions (see FAQs [E.21](#) and [E.24](#) and NIH Guide Notice [NOT-OD-18-160](#)).
- Clarify that disclosure is required for all financial interests received from a foreign institution of higher education or the government of another country (see FAQs [E.21](#) and [E.24](#) and NIH Guide Notice [NOT-OD-18-160](#)).
- The value of the SFI.
- Provide a distinction whether the SFI is from a publicly traded or non-publicly traded entity.
- Provide a description of the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- Provide an indication whether the SFI is related to any Public Health Service application and/or funded project and an explanation for the relatedness. Some information to consider:
  - The institution's designated official(s) makes the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research).
  - Per the preamble in the [Final Rule](#) (page 53261), "significantly" means "...the financial interest would have a 'material effect on the research'..."

Additionally, all investigators will be informed of the "FCOI Training" on the NIH's FCOI website prior to becoming an SSR officer or Board member. Every four years, or any time



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there is a change in FCOI policy, an officer or Board member is new to the institution, or an officer or Board member is not in compliance with the policy or management plan, they will be required to complete the FCOI Training on the NIH FCOI website.

#### DEFINITIONS

**SSR Board of Directors:** The business of this organization shall be managed by a Board of Directors consisting of six elected Regular Members and one elected Early-Stage Investigator (defined as within 10 years of completion of terminal degree) together with (1) the immediate Past President, (2) the President, (3) the Vice President, (4) the Vice President-Elect, (5) the Secretary, and (6) the Treasurer. These thirteen voting members of the Board of Directors must all be Regular Members of the Society. The Board of Directors shall be responsible for the control and management of the affairs, property, and interests of the Society, and may exercise all powers of the Society except as herein provided, in the Articles of Incorporation, or by statute expressly conferred upon or reserved to the Members. The Board of Directors shall act only in the name of the organization when it shall be regularly convened by its President after due notice to all the Directors and Officers of such meeting.

**SSR Executive Council:** The Executive Council shall consist of the immediate Past President, the President, the Vice President, the Vice President-Elect, the Secretary, and the Treasurer: Its function shall be to exercise all functions and powers of the Board of Directors between the meetings of the Board of Directors.

The Executive Council shall evaluate institutional conflict of interest situations; to develop, in collaboration with the appropriate SSR officials, conflict of interest management plans; to review and assist with the monitoring of management plans developed; to review reports and information relating to post-approval implementation and monitoring of conflict-of-interest management plans; and to recommend corrective actions and/or sanctions for non-compliance with this policy.

**SSR Conflict of Interest (COI) Disclosure Statement:** All SSR Board of Directors are required to complete and sign a COI Disclosure Statement. Board members are required to disclose any situations or areas in which it might appear that they have conflicting duties to other persons, products, or entities. Board members agree to take other steps, such as avoiding deliberation and resolution of certain issues or even withdrawing from their position with SSR, if it is determined those steps are necessary to protect against legal liability to the Society or to themselves personally.

**Financial Conflict of Interest (FCOI)** means a significant financial interest related to a program that could directly and significantly affect the design, conduct or reporting of research or grant.

**Institutional Conflict of Interest (ICOI):** A situation in which the financial or business interests of SSR, or of an SSR Official acting within his or her authority on behalf of the SSR,

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can inappropriately affect or reasonably appear to inappropriately affect the research, teaching, outreach, business transaction or other activities of the Society.

**Financial Interest** means anything of monetary value or potential monetary value held by the officer or Board member, the officer or Board member's spouse and/or dependent children, regardless of whether the value is readily ascertainable.

**Significant Financial Interest (SFI)** means the following financial or business interests of the Society:

1. *Royalty arrangements*: payments, including royalty payments and licensing fees, resulting from technology transfer, licensing, and business activities that, for each arrangement, exceed \$5,000 in the preceding twelve (12) month period;
2. *Non-publicly traded equity*: equity and ownership interests of any amount in any for-profit entity that is not publicly traded:
3. *Publicly-traded equity*: equity and ownership interests valued at greater than \$5,000 in the preceding twelve (12) month period in any publicly-traded, for-profit entity, except for equity held in the Society's endowment (please see note below); and
4. *Gifts greater than five thousand (\$5,000)* from any for-profit entity or philanthropic unit associated with a for-profit entity (please see note below).

**Note about gifts:** Gifts, pledges, and solicitation of gifts to the Society are important to its mission. However, no charitable donation can be contingent upon the outcome of any activities conduct by the SSR. SSR hereby affirms that it will not solicit or accept gifts that in any way limit the ability of its members to conduct and/or report the results of research in accordance with the highest scientific, medical, professional, and ethical standards.

The goal of this policy is not to preclude SSR from accepting philanthropy from companies that sponsor research or otherwise conduct business with the Society. Rather, the policy is intended to help SSR develop means of identifying and examining such circumstances, and of managing, through disclosures, separation of responsibilities, and as otherwise appropriate, any actual or apparent conflicts of interest that may result.

SSR hereby affirms that its investment managers are forbidden from communicating with SSR Officers, Board Members or SSR members concerning the conduct and interpretation of ongoing or planned research for the purpose of influencing investment decisions. Maintaining this robust "firewall" is essential for ensuring the core activities conducted by or on behalf of SSR are not affected, or perceived to be affected, by the Society's interests in maximizing the value of its endowment pool. If an individual becomes aware of a situation in which there



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appears to be a conflict of interest involving philanthropic gifts, solicitation of gifts, or management of the endowment pool, the individual must notify the SSR Executive Council for review and determination as outlined below.

5. Certain other payment or financial benefits: From time to time, SSR enters into contractual relationships with outside parties which include a payment or other financial benefit to the Society from the contracting party that are based on factors outside the course of business between the Society and the contracting party (e.g., philanthropic support for SSR). SSR recognizes that certain types of these contracts, if not properly managed or disclosed by the Society, and which because of the Society's unique position and relationships, may create the perception that SSR was improperly influenced to enter into the contract or endorses the contracting party as a "preferred provider" or may improperly influence consumer choices by third parties, in particular SSR members.

**Institutional Financial Interests** shall also mean the following financial or business interests of SSR Officers and Board members (and those of their spouse or partner):

1. Equity and/or ownership interests in publicly traded, for-profit entities that have a financial or other relationship (e.g. sponsor/supporter) with the SSR if the value exceeds \$5,000 in the preceding twelve (12) month period. Not included are equity or ownership interests in mutual funds and retirement accounts, as long as the SSR Official does not directly control the investment decisions made in these investment vehicles;
2. Equity (including stock, options, warrants), ownership, or founders' interests of any amount in non-publicly traded entities that have a financial or other relationship (e.g. sponsor/supporter) with the SSR;
3. Income, including royalties, equity, consulting fees, honoraria and gifts or other payments, from for-profit entities that have a financial or other relationship (e.g. sponsor/supporter) with the SSR, in the aggregate, exceed \$5,000 from each entity in the preceding twelve (12) month period;
4. Any fiduciary role with a for-profit entity, regardless of compensation or income, such as service on the board of directors, management role in a company or partnership (e.g., President, CEO, COO, or Treasurer) for entities that have a financial or other relationship (e.g. sponsor/supporter) with the SSR .
5. Any fiduciary role with a non-profit entity that has a financial or other relationship (e.g. sponsor/supporter) with the SSR that could reasonably lead to a potential institutional conflict of interest.



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## Review and Determination

Administration of FCOI matters will be handled by the SSR Executive Council. The Council shall be responsible for (i) the review of all reports of activities described above and all annual disclosures made by SSR Officials to determine whether there are Institutional Financial Interests that could lead to a potential ICOIs.

### 1. Review of the SSR's Institutional Financial Interest:

SSR shall use reasonable efforts to manage potential ICOI matters prior to finalization of the proposed SSR transaction (e.g., prior to the gift, contract, or sponsored project being executed or accepted) that gives rise to the potential ICOI. To do this, the Executive Director of the SSR shall, semi-annually, provide a list of entities with which there has been a disclosed Institutional Financial Interest of the SSR to the Executive Council.

The Executive Director will notify the Executive Council when a proposed transaction with one of the entities on the list arises so that they can review the proposed transaction and the related disclosure(s) and manage, if necessary, any identified ICOI in accordance with this policy prior to finalization of the proposed transaction.

SSR recognizes that some transactions will be finalized prior to a review and determination by the Executive Council. In these instances, the Institutional Financial Interests will still be reviewed by the Executive Director and any identified ICOI's will be managed in accordance with this policy to allow the transaction or relationship to continue uninterrupted while also appropriately mitigating or managing any potential ICOI concerns.

### 2. Review of Institutional Financial Interests of SSR Officials:

The Executive Director shall also collect and review all disclosures made by SSR Officials. If an SSR Official discloses an Institutional Financial Interest that is related to that Official's role and responsibilities, then the Executive Director shall assign the Disclosure for review by the Executive Council as outlined below.

### 3. ICOI Determination:

The Executive Director, under authority granted by the Executive Council, shall determine whether the Institutional Financial Interest could inappropriately affect or reasonably appear to inappropriately affect SSR Activities. In making the ICOI determination, the Executive Director shall consider whether the Institutional Financial Interests disclosed as outlined above have the potential to, or appear to, affect any of the following:

- Integrity of research or activity;
- Appropriate allocation of resources;
- Objectivity and independence of educational activities;

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- Independence of professional practice judgment; and
- Objectivity in business and contracting decisions.

If the Executive Director finds that an ICOI exists, then it shall also determine whether the ICOI shall be managed or eliminated.

To ensure efficiency, the Executive Council is authorized to delegate to the SSR President the authority to determine whether an Institutional Financial Interest constitutes an ICOI, the SSR President may determine whether the Institutional Financial Interest constitutes an ICOI without referral to the Executive Council.

### ICOI Management

The Executive Council, the SSR President or the Executive Director shall document its ICOI determination and, if applicable, a management plan, which shall specify the actions that have been, and/or shall be, taken to manage the ICOI. Examples of conditions and restrictions that may be imposed to manage an ICOI, either as a single condition or restriction, or as a combination of conditions and restrictions, and on either an interim or permanent basis include, but are not limited to:

1. Public disclosure of the ICOI (e.g., in public presentations or publications of the related research);
2. Disclosure of the ICOI to human participants, if applicable;
3. Appointment of an independent monitor capable and willing to take appropriate measures to protect the activities of the SSR against potential bias resulting from the ICOI;
4. Where the ICOI involves an SSR Official, formal recusal of the conflicted official from the chain of authority over the related project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator or staff, as well as communication of the recusal arrangements to the Official's superior and colleagues;
5. Where the ICOI involves an SSR Official, designation of a "safe haven" (e.g., a non-conflicted senior individual) with whom the investigator or staff can address ICOI-related concerns;
6. Reduction or elimination of the Institutional Financial Interest (e.g., sale of an equity interest); or
7. Severance of the relationship giving rise to the ICOI.

The Executive Director, Principal Investigator or SSR President shall communicate to the NIH summary information about the nature and amount of any Institutional Financial Interest related to human participants in research, along with the Executive Council's findings, ICOI determination and any institutional management plan approved by the Executive Council.

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The Executive Director, Principal Investigator or SSR President shall also, as deemed necessary, communicate summary information about the nature and amount of the Institutional Financial Interest, along with the Executive Council's findings, ICOI determination and any institutional management plan approved by the Executive Council to the SSR.

#### Additional Requirements

The following additional requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH. Reporting AFAR will provide to the PHS Awarding Component a FCOI report as outlined in the regulations: Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. AFAR will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria);
- Value of the financial interest 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;
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research;
- Key elements of the FCOI action plan Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:
  - Grant/Contract Number
  - PD/PI
  - Name of Investigator with FCOI
  - Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
  - Value of the financial interest 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
  - Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
  - Key elements of the FCOI action plan
- Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:
  - Status of the FCOI
  - Changes to the action plan
  - Justification that an FCOI no longer exists



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## NIH Reporting Requirements

If SSR is unable to satisfactorily manage a conflict of interest involving NIH funding, it will appropriately notify NIH's Office of the General Counsel.

SSR will send, initial and revise FCOI reports, including all required information defined in the regulation and or NIH's FAQ H.5 to the NIH via the eRA Commons FCOI Module for the Society and its subrecipients, if applicable:

- Prior to the expenditure of funds;
- Within 60 days of new, or newly identified FCOIs for existing Officers or Board members;
- At least annually provide a status of the FCOI and any changes to the management plan, until completion of the project;
- After a retrospective review to update a previously submitted report, if new information is discovered following completion of the project;

SSR will notify NIH promptly if:

- bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of bias in accordance with the regulation.
- an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased on the design, conduct or reporting of the PHS/NIH-funded research and take appropriate corrective action for non-compliance.

## Retrospective Review

- A retrospective review will be completed within 120 days of SSR's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or management in a timely manner, including:
  - Failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute an FCOI;
  - Failure by the Institution to review or manage such an FCOI;
  - Failure by the Investigator to comply with the FCOI management plan;
- The retrospective will review will include the following element:
  - Project #
  - Project Title
  - PD/PI or contact (if PD/PI model is used)
  - Name of Investigator with the FCOI
  - Name of the entity with which the Investigator has an FCOI
  - Reasons for the retrospective review
  - Detailed methodology used for the retrospective review
  - Findings and conclusion of the review

## Subrecipient Requirements



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SSR, where applicable will establish, via a written agreement, whether the subrecipient will follow SSR's FCOI policy or the FCOI policy of the subrecipient. The agreement will include a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIS to the NIH as required by the regulation.

#### Public Accessibility Requirements

SSR will make its FCOI policy publicly accessible and will post the FCOI policy on SSR's website. It will be updated annually and within 60 days of a newly identified FCOI and remain available for three years from the date the information was most recently updated.

SSR will make available information concerning identified FCOIs held by senior/key personnel publicly accessible prior to the expenditure of funds.

#### Records

SSR will maintain all records related to the implementation of this policy for at least three years after:

- the date of creation;
- the date of termination or completion of a research award or contract;
- the submission of the final expenditures report; or
- the date of final resolution of any investigation, audit, or similar action involving the records.

#### NONCOMPLIANCE / FAILURE TO DISCLOSE

Non-compliance with this policy, and any disciplinary action resulting due to non-compliance with this policy, will be managed in accordance with applicable SSR policies and processes as determined by the status of the individual involved in the non-compliance.

#### FURTHER INFORMATION

For questions, additional detail, or to request changes to this policy, please contact the Executive Director of SSR ([executivedirector@ssr.org](mailto:executivedirector@ssr.org)).

*Policy created: June 30<sup>th</sup>, 2021*