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## 1.0 PURPOSE

This policy is intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research performed under Public Health Service (PHS) grants, cooperative agreements and contracts will be free from bias resulting from Investigator Conflicts of Interest, including Financial Conflicts of Interest.

This policy implements the requirements of certain federal regulations, including “Promoting Objectivity in Research” (42 C.F.R. Part 50, Subpart F) that addresses PHS Research grants and cooperative agreements, and “Responsible Prospective Contractors” (45 C.F.R. Part 94) that addresses PHS Research contracts.

## 2.0 SCOPE

The policy applies to all research grants, cooperative agreements, or contracts funded directly or indirectly by the Public Health Service of the U.S. Department of Health and Human Services (PHS), including the National Institutes of Health (NIH), Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC) and all other PHS agencies. The policy applies whether ASELL receives the funding directly from a PHS agency or receives funding as a Subrecipient or subcontractor. It also applies to research funded by other agencies or foundations that use PHS Financial Conflict of Interest regulations in their award terms.

The policy applies to all research projects awarded by Funding Agencies other than Phase One SBIR or STTR awards.

## 3.0 REFERENCES

42 CFR Part 50, Subpart F - Promoting Objectivity in Research

45 CFR Part 94 - Responsible Prospective Contractors

POL350.02-1 - SFI Disclosure Form


POL350.02-2 – FCOI Reporting Form

## 4.0 DEFINITIONS

**Covered Research** means Research performed by ASELL, or by Subrecipients or subcontractors to ASELL, that is sponsored directly or indirectly by a PHS Awarding Component or other Funding Agency through a grant, cooperative agreement or contract.

**Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Covered Research.

**FCOI Report** means an Institution’s report of a financial conflict of interest to a Funding Agency.

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**Funding Agency** means a PHS component that sponsors Research, or another agency or foundation that uses PHS FCOI regulations in their award terms to sponsor Research.

**Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of ASELL.

**Investigator** means the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Covered Research, or is proposed for such Covered Research, and which may include, for example, collaborators or consultants.

**Key Personnel** means the PD/PI and any other personnel considered to be essential to work performance and identified as key personnel in the proposal, contract, grant application, progress report or any other report submitted to the Funding Agency.

**Management Plan** means a plan for taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**Policy Coordinator** means the individual designated by the ASELL President to coordinate review of SFI Disclosures. The Policy Coordinator is the ASELL Vice President, Technology Development

**Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development.

**Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or registered domestic partner and/or dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- 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;
  - 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
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- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

SFI does not include:

- Salary, royalties, or other remuneration from ASELL;
- Any ownership interests in ASELL;
- Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions for these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities.

**SFI Disclosure Form** means the form ASELL utilizes to report Significant Financial Interests (POL350.02-1)

**Sponsored Travel** means travel related to the Investigator's Institutional Responsibilities which is paid by a party other than ASELL on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available; 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.

**Subrecipient** means a non-Federal entity that receives a subaward or subcontract to carry out part of a Covered Research project from an awardee working directly under Funding Agency sponsorship. The term includes consortium participants. For clarity, Subrecipients do not include entities that provide commercial items or services if that is their sole contribution to the Covered Research.

## 5.0 FCOI POLICY IMPLEMENTATION

This paragraph describes the implementation of ASELL's responsibilities to identify, manage, and report any Financial Conflicts of Interest related to Covered Research.

Prior to the expenditure of any newly awarded funds for Covered Research, a review of SFI Disclosures from all Investigators associated with the newly awarded Covered Research will be performed, and Management Plans will be established for any SFI that results in a positive finding for FCOI.

An Investigator who is new to the company or is newly assigned to a Covered Research project must submit an SFI Disclosure prior to participating in Covered Research. For such new Investigators, or for Investigators already participating in Covered Research who disclose new SFI, ASELL will review the disclosures and if necessary, implement Management Plans within 60 days of disclosure submittal.

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Depending on the nature of the SFI, interim measures regarding the Investigator's participation in the Covered Research project may be taken between the date of disclosure and the completion of the review.

#### 5.1. Investigator Training

Each Investigator participating in Covered Research on behalf of ASELL must understand their responsibilities for disclosing Significant Financial Interests and complying with this policy. Each Investigator will perform training on this policy prior to engaging in Covered Research and at least every four years, and immediately when any of the following applies:

- This FCOI policy or the associated Financial Disclosure Form are revised in any manner that affects the requirements of Investigators;
- An Investigator joins the Company; or
- The Company finds that an investigator is not in compliance with this FCOI policy or management plan (See Section 5.5).

Training will consist of each Investigator reading the policy and providing written acknowledgement that the Investigator understands the policy and his/her obligations under it. Additional information, including an FCOI tutorial, is available through the NIH website.

(<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>),

#### 5.2. Investigator Disclosure of Significant Financial Interests

Full and prompt disclosure of Significant Financial Interests is critical to complying with this policy. There are three types of disclosures that all utilize the ASELL SFI Disclosure Form:

1. Proposal-Related Disclosures – Prior to submitting a proposal or grant request for funding to support Covered Research, the Principal Investigators and other Investigators associated with the funding request must disclose their Significant Financial Interests.
2. Annual Disclosures – Investigators contributing to Covered Research must disclose their Significant Financial Interests to ASELL on an annual basis during the period of the Covered Research.
3. Ad-Hoc Disclosures which occur in two situations:
  - a. Investigators who join an ongoing Covered Research project must disclose their Significant Financial Interests prior to initiating participation in the Covered Research.
  - b. Investigators must disclose any new Significant Financial Interest within 30 days of the date on which the new SFI is acquired or arises (e.g., through purchase, marriage or inheritance).

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In addition to the above SFI disclosures, PHS regulations require Investigators to disclose any Sponsored Travel. The Sponsored Travel disclosure will include, at a minimum, the purpose of the trip, the identify of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure the FCOI Policy Coordinator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI.

### 5.3. Identification of Financial Conflicts of Interest

SFI Disclosure Forms are submitted to the Policy Coordinator. Initial review will be performed by at least two management representatives selected from the VP Technology Development, VP Operations, Chief Scientist, and Director of Quality Assurance. No reviewer may assess SFI Disclosure Forms for themselves or for a Covered Research project for which they are an Investigator. The selected reviewers will review each SFI Disclosure Form and make a determination of whether reported Significant Financial Interests result in a Financial Conflict of Interest by evaluating whether the SFI:

- Is related to Covered Research – i.e. it could reasonably be determined that the SFI could be affected by the Covered Research, or is in an entity whose financial interest could be affected by the research; and
- Could directly and significantly affect the design, conduct, or reporting of the Covered Research.

The reviewers may involve the Investigator in determining whether the SFI is related to Covered Research. The reviewers may also consult with appropriate company personnel, outside advisors or governmental officials when evaluating an SFI Disclosure for a Financial Conflict of Interest.

In determining whether an Investigator's SFI is an FCOI, the reviewers will consider all available evidence in light of the following concepts, in addition to any other concepts the reviewers may reasonably consider:

#### Protected Interests:

- Research integrity
- Safety of human subjects
- ASELL's reputation
- The Investigator's reputation

#### Relationship between the SFI and the Covered Research:

- Is the subject of the SFI or its products or services involved in the research, and how?
  - Is the SFI in a diversified enterprise generally, or in a specific division or subsidiary more closely related to the research?
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#### Nature of the SFI

- Equity, cash compensation, or in-kind compensation?
- Part of a diversified portfolio or a specific investment?
- Publicly-traded or private company?
- Does compensation exceed fair market value?

#### Likelihood of influence

- Role of the Investigator in the research
- Potential gain to Investigator if research yields particular results
- Safeguards built into design

If the reviewers jointly determine that no FCOI exists, the resulting negative finding will be filed in the Company's FCOI files, and no further review is required. If at least one reviewer determines that a FCOI exists, a positive finding will be declared, and a written justification will be provided. Positive findings can be appealed (See Section 5.4) or managed (See Section 5.5).

#### 5.4. Investigator Appeal of Positive Finding

Investigators may appeal a positive finding to the company President. To conduct an appeal review, the President will select two internal or external independent reviewers who did not participate in the initial review and who are not involved with the Covered Research. The President and independent reviewers will make a final determination as to whether to confirm the FCOI or to over-ride the previous positive finding and conclude that no FCOI exists, in which case the resulting negative finding will be filed in the Company's FCOI files. Confirmed positive findings require a Management Plan (See Section 5.5) and reporting to PHS (see Section 5.6).

#### 5.5. Management of Financial Conflicts of Interest

A Management Plan must be established for any Investigator with a FCOI related to their participation in Covered Research. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of the identified financial interests (e.g. when presenting or publishing the research);
  - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - 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;
  - Modification of the research plan;
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- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severing relationships that create financial conflicts.

The Company will monitor investigational compliance with the Management Plan on an ongoing basis until the completion of the Covered Research project.

#### 5.6. Reporting Requirements to PHS

Prior to expending any funds under a newly awarded Covered Research project, the Company must report the existence of any FCOI to the applicable Funding Agency and ensure that the Company has implemented a management plan in accordance with the FCOI regulations and this policy. If the Company identifies an FCOI and eliminates it prior to the expenditure of funds, the Company is not required to submit an FCOI report to the respective agency.

For any new FCOI identified subsequent to an initial FCOI Report during an ongoing Covered Research project, ASELL will provide an FCOI Report within 60 days of identification of the new FCOI.

For any previously reported Financial Conflicts of Interest, an updated FCOI report will be submitted annually that addresses the status of the FCOI and any changes to the Management Plan. Annual updates will be submitted for the duration of the Covered Research project or until a submitted FCOI report explains why the FCOI no longer exists.

Any submitted FCOI Report will include sufficient information to enable the Funding Agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of Management Plan. FCOI Reports will include, at a minimum, the items enumerated in the appropriate paragraphs of the FCOI regulations identified in Section 3.0.

#### 5.7. Compliance

Whenever a SFI is identified that was not disclosed in a timely manner by an investigator or, for any reason was not previously reviewed during a Covered Research project, the SFI will be reviewed within 60 days of its identification. If a FCOI is found to exist, a Management Plan will be implemented on an interim basis that specifies the actions that have been and will be taken to manage such FCOI going forward.

Whenever a FCOI is not identified or managed in a timely manner, including failure of an Investigator to disclose a SFI that is determined to constitute an FCOI, failure by the institution to review or manage such a FCOI, or failure by the Investigator to comply with a Management Plan, a retrospective review of

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the Investigator's activities and the relevant Covered Research will be completed within 120 days of the determination of non-compliance, to determine whether any Covered Research conducted during the time period of the non-compliance was biased in the design, conduct or reporting of such research. Retrospective reviews will include, at a minimum, the items enumerated in the appropriate paragraphs of the FCOI regulations identified in Section 3.0.

Based on the results of the retrospective review, the previously submitted interim FCOI report will be updated, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Funding Agency will be promptly notified, and a mitigation report prepared. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the company's plan of action to eliminate or mitigate the effect of the bias.

For clinical research projects supported by PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI regulations, the Company must require the Investigators to disclose the FCOI in each public presentation (such as articles, manuscripts, and oral presentations) of the results of the research and to request an addendum to previously published presentations.

All persons subject to this FCOI policy are expected to comply with it fully and promptly. If an Investigator has violated this FCOI policy, for example, by failure to disclose a SFI, the Company may take disciplinary or other appropriate action. Intentional disregard for this policy, including non-adherence to the agreed upon management plan, constitutes serious misconduct and may be the basis for further administrative or legal action.

#### 5.8. Subrecipient Requirements

Covered Research performed by Subrecipients (e.g. subcontracts or consortium members) must comply with the regulations identified in Section 3.0. Compliance may be achieved through a Subrecipient's FCOI Policy that is compliant with the regulations or by the Subrecipient's Investigators complying with the ASELL policy. A subaward, subcontract or other authorizing agreement issued to a Subrecipient will specify which organization's policy will apply to the Subrecipient's Covered Research.

If the Subrecipient's Investigators are to comply with the Subrecipient's FCOI policy, the Subrecipient must certify as part of the authorizing agreement that its policy complies with the regulations identified in Section 3.0. If the Subrecipient cannot provide such certification, the agreement will state that



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Subrecipient Investigators are subject to ASELL's FCOI policy for disclosing SFIs that are directly related to the Subrecipient's work under the agreement.

Additionally, if the Subrecipient's Investigators are to comply with the Subrecipient's financial conflicts of interest policy, the authorizing agreement must specify time period(s) for the Subrecipient to report all identified FCOI to ASELL. Such time period(s) will be sufficient to enable ASELL to provide timely FCOI reports, as necessary, to the Funding Agency.

Alternatively, if the Subrecipient's Investigators are to comply with the ASELL FCOI policy, the authorizing agreement must specify time period(s) for the Subrecipient Investigators to perform required training and submit all Investigator SFI disclosures to ASELL. Such time period(s) will be sufficient to enable ASELL to comply timely with its review, management, and reporting obligations.

ASELL will report to the Funding Agency any FCOI that is identified by any Subrecipient, subcontractor, or collaborator to ASELL in the manner required under the FCOI regulations, prior to the expenditure of newly awarded funds and within 60 days of any subsequently identified FCOI.

#### 5.9. Public Disclosure of ASELL FCOI Policy and Financial Conflicts of Interest

The ASELL FCOI policy will be posted on the ASELL website.

ASELL will ensure public accessibility regarding any Financial Conflict of Interest associated with any Key Personnel on a Covered Research project. Public accessibility may be provided by posting the information on the ASELL website, which if used will be updated at least annually, or by providing a written response to any requestor within five business days of a request.

Key Personnel FCOI information must be accessible prior to expenditure of any Covered Research project funds, or within 60 days of receipt or identification of information concerning any additional Key Personnel SFI if the SFI is determined to create a FCOI.

The publicly available information will include, at a minimum, the following:

1. Investigator's name;
  2. Investigator's title and role with respect to the Covered Research;
  3. Name of entity in which the SFI is held;
  4. Nature of the SFI;
  5. Approximate dollar value of the SFI (dollar ranges are permissible: \$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.
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If Key Personnel FCOI disclosure information is posted to the ASELL website, the website will note that the information provided is current as of the date listed and is subject to updates on at least an annual basis and within 60 days of the receipt of a new Key Personnel FCOI. If ASELL receives written requests for Key Personnel FCOI information, the written response will note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the identification of a new Key Personnel FCOI, which should be requested subsequently by the requestor.

Information concerning Key Personnel FCOI will remain accessible for at least 3 years from the date that the information was most recently updated.

5.10. Maintenance of Records

ASELL will maintain all Disclosure of SFI Forms and all related records regarding reviews and actions taken with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the Funding Agency, or, for other such periods of time as may be required under 45 CFR 75.361.

Records will be made available to funding agencies for review per the requirements of the regulations referenced in Section 3.0.

**6.0 COMPANY PRESIDENT ADMINISTRATIVE PREROGATIVE**

During the course of any inquiry or investigation, the company President will have the prerogative to take interim administrative actions, as appropriate, to protect external funds and ensure that the purposes of the external financial assistance are protected.