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Financial Conflict of Interest Policy

Purpose

Profusa, Inc. endeavors to promote objectivity in research by establishing standards that preserve the integrity of research, protect the rights and safety of research subjects, and prevent bias in the design, conduct and reporting of research sponsored by the Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS), (i.e. NIH).

Scope

This policy applies to all Profusa employees and contractors who are Investigators involved in the design, conduct or reporting of research. Designated provisions of this policy apply only to Investigators applying for or conducting research funded by the Public Health Service. Investigators who conduct studies regulated by the Food and Drug Administration or who conduct research funded by the other federal agencies, including the National Science Foundation, are subject to agency-specific regulations relating to reporting Financial Interests and/or Financial Conflicts of Interest (non-PHS) in research.

I. POLICY

Profusa, Inc. endeavors to create a research climate that promotes objectivity in research by establishing standards such that the design, conduct and reporting of Public Health Service funded research is free from bias resulting from financial conflict of interest (FCOI).

This policy is applicable to each employee who is planning to or is participating in research activity that is either partially or wholly supported by PHS funds. Each such employee must:

1. **disclose** his or her significant financial interests (SFI) in non-Profusa entities that would appear to be related to the employee's professional responsibilities on behalf of Profusa;
2. **comply** with a FCOI management plan, if a FCOI is identified; and
3. **undergo** FCOI training, at least once every four years.

Disclosure of SFI is essential for Profusa to determine if a FCOI exists, and in cases of FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with FCOI management plan may subject the employee to employment discipline including, without limitation, suspension or termination of employment.



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II. DEFINITIONS

A. *Financial conflict of interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS funded research.

B. *Significant Financial Interest (SFI)* exists if the value of remuneration received by the employee, employee's spouse or dependent children that reasonably appear to be related to the employee's Profusa responsibilities exceeds \$5,000 or may be a combination of remuneration that when totaled exceeds \$5,000;

1. Including:

- Salary or other payments for services (e.g., consulting fees or honoraria) received in the 12 months preceding disclosure;
- Equity interests (e.g., stocks, stock options or other ownership interests) during the 12 months preceding the disclosure; however, equity interest in a non-publicly traded entity, no matter the amount, constitutes an SFI; and,
- Income from intellectual property rights (e.g., royalties from patents or copyrights) owned by the employee.
- Travel expenses reimbursed or paid by an entity other than Profusa. Third party reimbursed or sponsored travel that is related to the employee's responsibilities (i.e., administrative, research, or clinical activities) must be disclosed to Profusa. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by Profusa and does not apply to travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medial center, or a research institute that is affiliated with an Institution of higher education.

2. Excluding

- Salary, royalties, stock options or other remuneration from Profusa;
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, sponsored by a federal, state, or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research



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- institute that is affiliated with an Institution of higher education;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions; and,
- Unlicensed intellectual property owned by the employee that does not generate income. Note that Intellectual property owned by Profusa is excluded.

C. Employee's professional responsibilities on behalf of Profusa means conducting research, submitting patent applications, publication, technical committee membership and, teaching as adjunct faculty at an Institute of higher education.

III. PROCEDURE

Employees who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion, either to a member of the Profusa Management Team or the designated Profusa FCOI official. The designated Profusa FCOI official will determine whether the SFI constitutes an FCOI, based on guidance set by the Management Team. Consistent with the Protocol for Handling Financial Conflict of Interest, if the SFI is determined to be an FCOI, the Management Team will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via a FCOI report.

As a part of the FCOI management plan, the Management Team will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Employees with an identified FCOI must comply with the FCOI management plan.

IV. Protocol for Handling Financial Conflict of Interest

This protocol outlines the procedure that will be followed as per regulation Title 42 Code of Federal Regulations (CFR), Part 50 Subpart F.

1. Who is required to disclose financial interests

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests ("PHS-funded Investigators").

2. SFI disclosure



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PHS-funded Investigators are required to disclose SFIs to either a member of the Profusa Management Team or the designated Profusa FCOI official, as follows:

1. Employees planning to participate in PHS-funded research are required to disclose all SFI's prior to submission of an application for PHS-funded research.
2. Once the research project has been funded all PHS-funded investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI,
 - o When a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project.
3. All PHS-funded investigators shall submit an updated SFI disclosure annually.
4. SFI disclosures (except travel) must include the following information:
 - o Identity of the sponsor/organizer; and
 - o Nature of SFI (e.g., salary, license income, stock).
5. Externally funded travel also constitutes SFI, and therefore disclosure requirements apply. That is, PHS-funded investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
 - o Purpose,
 - o Identity of the sponsor/organizer,
 - o Destination, and,
 - o Duration.

3. Review of disclosures

All SFI disclosures, including those submitted by a new investigator who joins an ongoing PHS-funded project or for an existing investigator who discloses a new SFI, will be reviewed by the designated Profusa FCOI official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The designated Profusa FCOI official may involve the relevant investigator in the review and request additional information from the investigator.

When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the designated Profusa FCOI official will determine if FCOI exists, develop, and implement a management plan within sixty (60) days after the identification of the SFI. In addition, the designated Profusa FCOI official will conduct a retrospective review of SFIs for the PHS-funded



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investigator within one hundred twenty (120) days and document it.

4. Management of FCOI

For each disclosure that leads to determination of FCOI, the Profusa Management Team will discuss and approve the implementation of a management plan developed by the designated Profusa FCOI official. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:

1. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
2. Conditions of the management plan (see examples below);
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
5. How the management plan will be monitored to ensure PHS-funded Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
- 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;
- Change of personnel or personnel responsibilities, or disqualifications 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
- Severance of relationships that create financial conflicts.

5. Reporting FCOI to PHS Awarding Component (e.g. the NIH)

Based on the FCOI management plan, the designated Profusa FCOI official will submit an initial FCOI report to the PHS-funding component. The report will be submitted, for example using eRA



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Commons for NIH, and consist of all elements required by the regulation.

The FCOI report for will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

6. Training Requirements for FCOI

PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations, as follows:

1. When a new employee joins Profusa;
2. Prior to participating in PHS-funded research, and at least once every four years;
3. When the Profusa FCOI policy changes in a manner that effects PHS-funded Investigator disclosure or compliance requirements; and,
4. If the Profusa Management Team determines that a PHS-funded Investigator is not compliant with the FCOI Policy or an FCOI Management Plan.

NIH web-based training, available at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>, will be used. Employees must save and print the FCOI Certificate as proof of completion.

7. Sanctions for violation of policy

Disclosure of SFI is essential for Profusa to implement its FCOI policy. If a PHS-funded Investigator fails to comply with this policy and appears to have biased the PHS-funded research, the Profusa Management Team will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the employee may be subject to employment discipline including, without limitation, suspension or termination of employment. In any case, the PHS-funding agency will be promptly notified.

8. Retention of records



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Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

9. Subrecipient compliance

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting.

10. Public Accessibility

As required by PHS regulation, the Profusa FCOI policy is being made accessible on Profusa website.

If a PHS-funded investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the website, as follows:

1. Include the minimum elements required by the regulation;
2. Update within sixty (60) days of a newly identified FCOI;
3. Update at least annually; and
4. Remain available for three (3) years from the date the information was most recently updated.

V. ADMINISTRATION

The designated Profusa FCOI official is responsible for administration of this policy.