

RASopathies Network (RASNet)**Institutional Policy on Financial Conflict of Interest (FCOI)****I. Purpose**

The Code of Federal Regulation promoting objectivity in research (42 CFR Part 50 Subpart F) requires institutions to develop an FCOI Policy that will be maintained and enforced and that meets regulatory requirements.

The requirements promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from any conflicting financial interest of an investigator.

The purpose of this document is to describe RASopathies Network (RASNet hereafter) FCOI policy guidelines to ensure compliance with all regulatory requirements.

This policy will apply to Board of Directors and non-Director volunteer members of RASNet who are planning to participate in, or are participating in, Public Health Service (PHS)/National Institutes of Health (NIH) funded research. This includes R13-supported conferences.

When applying for funding, RASNet will certify, that it:

- Has an up-to-date, written and enforced administrative process to identify and manage FCOI.
- 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.

II. Definitions

The following are considered key definitions in understanding the federal regulations of FCOI as it pertains to federally funded research. A complete list of official definitions can be found at [42 CFR 50.603](#).

Institution-

A domestic, foreign, public, or private (not Federal) entity that applies for or receives PHS/NIH grants or cooperative agreements for research. For the purposes of this policy guidance, RASNet is considered an Institution. The Board of Directors members of RASNet, as set forth in the RASNet Bylaws, will implement Institutional policies described herein.

Investigator-

The Project Director/Principal Investigator (PD/PI) and any other person who is responsible for the design, conduct, or reporting of research funded by PHS/NIH, which may include collaborators or consultants. Senior/Key Personnel means the PD/PI and any other person identified by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

Research-

Any activity for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award. This includes NIH-supported research conferences.

Financial conflict of interest (FCOI)-

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Significant financial interest (SFI)-

(1) A financial interest consisting of one or more of the following interests of the Investigator (or their 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 their spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Upon receipt of income related to **intellectual property rights and interests** (e.g., patents, copyrights)

(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)¹, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. RASNet will determine if further information is needed, including a determination or disclosure of monetary value, or whether the travel constitutes an FCOI with the PHS-funded research. RASNet will limit the disclosure requirement for reimbursed or sponsored travel to the de minimis threshold of \$5,000, when aggregated per entity.

¹ the reference is made to a United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

(3) SFI Exclusions:

(i) salary, royalties, or other remuneration paid by RASNet to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

(ii) intellectual property rights assigned to RASNet and agreements to share in royalties related to such rights;

(iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization. -- This exclusion does not apply given that RASNet is a non-profit organization;

(iv) 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;

(v) 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)¹, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or

(vi) income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a)¹, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

III. RASNet's institutional responsibilities include:

- Establishing standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.
- Maintaining an up-to-date, written, enforced policy that complies with the FCOI regulation and making policy publicly accessible.
- Maintaining records of disclosures of FCOI, review and response to such disclosures.
- Designating an Institutional Official to solicit and review disclosure statements from Investigators planning or participating in PHS/NIH-funded research.
- Providing guidelines to identify COI.
- Developing a management plan in the event of an FCOI or SFI disclosure.
- Informing investigators of the regulation, the FCOI policy, and their responsibilities for disclosure of SFIs.
- Facilitating Investigator FCOI re/training (required every 4 years unless there are policy changes, compliance issues, or new investigator).
- Providing initial and ongoing FCOI reports to NIH prior to expenditure of funds, during the period of the award if a new FCOI arises, or annually.
- Making a written FCOI policy available on our website along with reported FCOIs.
- Develop a plan for handling noncompliance through retrospective review, mitigation and reporting.

IV. Training

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest.

Investigators are required to complete FCOI training prior to engaging in research related to a PHS-funded grant or contract. Training is required every four years, or in a timely manner if: RASNet changes its FCOI policy; an Investigator is new to RASNet; RASNet finds an Investigator noncompliant with the FCOI policy or management plan. Training will involve reading through this policy document and completing the NIH tutorial. The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Completion of training will be documented and archived.

Additional training materials may be consulted on the appropriate NIH website pages (e.g., <https://grants.nih.gov/grants/policy/coi/index.htm>)

V. Disclosure, Review and Monitoring

- A. Prior to submitting any grant applications, the PI and Co-Investigators will be required to disclose any SFIs (or those of spouse and dependent children) in writing on an FCOI Disclosure Form². RASNet will solicit and review SFI disclosures from the previous twelve months and ensure disclosures are reported and filed appropriately, or if there are none, will document and archive.
- B. If RASNet determines that there is potential conflict of interest that could bias objectivity in design, conduct, or reporting of research, then steps will be taken to determine what measures are needed to address the SFI identified in the FCOI Disclosure Form². A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of (but not limited to) the following actions to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:
 - Public disclosure of significant financial interests;
 - Review of research protocols by independent reviewers;
 - Monitoring of research by independent reviewers;
 - Modification of research plan;
 - Disqualification from participation in all or a portion of the research funded;
 - Divesture of significant financial interests;
 - Severance of relationships that create actual or potential conflicts.
 - Management plans are required to be signed by the Investigator and the Board members. Compliance of the management plan shall be monitored regularly.
- C. Investigators shall provide FCOI disclosures annually or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new FCOI Disclosure Form(s)² within 30 days of discovering or acquiring the new SFI. It is the PI's responsibility to ensure that any newly acquired Investigator on a research project submits the required FCOI Disclosure Form² to RASNet.
- D. Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, RASNet will make recommendations regarding the impositions of sanctions or disciplinary proceedings against the violating individual. In addition, RASNet shall follow Federal regulations regarding the notification of the sponsoring agency in the event an

² FCOI Disclosure Form is available in Appendix A of this policy document

Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

- E. Records of Investigator FCOI disclosures, and of actions taken to manage actual or potential conflicts of interest, shall be retained in the RASNet digital archive for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 75.361 for different situations.
- F. Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If an SFI is identified by the sub-award recipient, they are required to notify RASNet of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.
- G. RASNet is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:
 - i. Initial report – prior to RASNet’s expenditure of any funds under a NIH-funded research project, RASNet must provide to the NIH an FCOI report³ regarding any Investigator SFI found by RASNet to be a financial conflict of interest in accordance with the regulation.
 - ii. During on-going NIH-funded research projects – RASNet shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If an FCOI was not disclosed in time, RASNet shall submit an FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
 - iii. For any FCOI previously reported to the NIH, RASNet shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

VI. Public Accessibility of FCOI Policy and FCOI Information

RASNet shall make its policy on Financial Conflict of Interest in PHS-funded research publicly available via their website <https://rasopathiesnet.org/>.

For more information, visit the following links:

NIH FCOI overview <https://grants.nih.gov/grants/policy/coi/index.htm>

NIH FAQs <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>

NIH FCOI Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

³ An FCOI report must include the elements shown in Appendix B of this policy document.

Appendix A

Financial Conflict of Interest (FCOI) Disclosure Form
(Applicable ONLY to Public Health Service (PHS)-Supported Investigators)

Full Name: _____

RASNet Position: _____

Proposal Title/#: _____

This PHS FCOI Declaration must be filed by each Investigator who is planning to participate in PHS-funded research no later than at the time of application for PHS-funded research, and at least annually. Additional PHS FCOI Disclosure forms shall be filed for new Significant Financial Interests (SFI) and updated information from a previously disclosed SFI, as soon as such situations become known, and not later than thirty (30) days after discovery or acquisition of the SFI.

A *Significant Financial Interest (SFI)* is defined as the receipt by you, your spouse, or your dependent children of any of the following:

- Income that exceeds \$5,000 from any outside entity, measured on a rolling 12-month basis. This may be one payment from a particular company of more than \$5,000, or multiple payments from the same company that in the aggregate exceed \$5,000 and are received within the previous 12 months.
- Acquisition of equity in a public company that exceeds \$5,000 in value;
- Aggregated income and equity/ownership interest from a public company that exceeds \$5,000, as measured on a rolling 12-month basis;
- ANY equity/ownership interest in a privately-held company;
- An income that exceeds \$5,000 from rights in intellectual property, as measured on a rolling 12-month basis;
- All reimbursed and sponsored travel that exceeds \$5,000, as measured on a rolling 12-month basis.

Excluded from this definition are payments (including travel) received from RASNet. Also excluded from this definition are payments received from any of the following entities, provided these payments are received for teaching engagements, lectures, seminars, or services on advisory committees or review panels:

- Government agencies, US institutions of higher education and research institutes affiliated with them, Academic teaching hospitals, Medical centers

Further, you do not have to report:

- Salary, royalties, travel, or other remuneration from RASNet
- Income from investment vehicles over which you do not exercise control, such as mutual funds and retirement accounts

I certify that I have read the RASNet FCOI Policy *and* completed training through the NIH tutorial.

Date of completion: _____

Is this an: Annual FCOI Declaration ____? **OR:** Additional FCOI Declaration (to report information not reported on annual FCOI Declaration) ____?

Do you, including your spouse and dependent children, have any Significant Financial Interests (SFIs) related to your responsibilities or research conducted at RASNet?

Yes, I have Significant Financial Interests to report. (Please provide information about your SFIs including reimbursed and sponsored travel on the next page)

No, I have no Significant Financial Interests, including travel, to report.

Signature: _____

Date: _____

Interest/Activity Type	Entity Name	Interest/ compensation/ reimbursement amount	Describe interest/activity (person holding interest, work performed...)
Equity/Ownership (stock, stock options...)			
Remuneration (consulting fees, honoraria...)			
Associations, Memberships, Positions (board of directors, offices...)			
Intellectual Property rights/ Royalty Income (not via RASNet)			
Travel	Destination/Duration/Purpose:		

Completed by
Signature: _____

Date: _____

Appendix B

Elements of an FCOI report

- Grant number;
- PD/PI or contact PD/PI;
- Name of Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for RASNet's determination that the financial interest conflicts with such research; and
- Key elements of RASNet's management plan.