RIPHI RHODE ISLAND PUBLIC HEALTH INSTITUTE

Financial Conflict of Interest Policy for NIH-Funded Research

1. Purpose

The Rhode Island Public Health Institute ("RIPHI") is committed to conducting research with the highest standards of scientific integrity, objectivity, and public trust.

The purpose of this policy is to establish procedures for identifying, reviewing, managing, and reporting financial conflicts of interest that could affect the credibility and integrity of our organization's staff and partners. This policy complies with requirements put forth in the National Institutes of Health ("NIH") guideline 42 CFR Part 50, Subpart F, *Promoting Objectivity in Research*.

2. Scope

This policy applies to all NIH-funded grants and cooperative agreements subject to 42 CFR Part 50, Subpart F, and to each Investigator who is planning to participate in or is participating in NIH-funded research conducted through RIPHI.

For purposes of this policy, an Investigator includes the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research or proposed NIH-funded research.

This policy also applies, as appropriate, to Investigators working through subrecipients, subcontractors, consortium members, or collaborators participating in RIPHI's NIH-funded research.

3. Definitions

Financial Conflict of Interest ("FCOI") means a Significant Financial Interest that RIPHI reasonably determines could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Institutional Responsibilities means an Investigator's professional responsibilities performed on behalf of RIPHI, including, as applicable, research, research consultation, clinical or professional practice, teaching or training, administration, and service on institutional committees or panels.

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of

NIH-funded research or proposed NIH-funded research. This determination is based on an individual's responsibilities rather than job title.

Senior/Key Personnel means the project director/principal investigator and any other person identified as senior/key personnel by RIPHI in a grant application, progress report, or other report submitted to NIH.

Significant Financial Interest ("SFI") means a financial interest consisting of one or more of the following interests of the Investigator, the Investigator's spouse, or dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities:

A. Publicly traded entities: An SFI exists when the value of remuneration received from an entity during the 12 months preceding disclosure, together with the value of any equity interest in the entity as of the date of disclosure, exceeds $5,000. Remuneration includes salary and payments for services not otherwise identified as salary, including consulting fees and honoraria. Equity interests include stock, stock options, and other ownership interests.

B. Non-publicly traded entities: An SFI exists when the value of remuneration received from an entity during the 12 months preceding disclosure exceeds $5,000, or when the Investigator, spouse, or dependent children hold any equity interest in the entity.

C. Intellectual property: An SFI includes intellectual property rights and interests, including patents and copyrights, upon receipt of income related to those rights and interests.

D. Reimbursed or sponsored travel: Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities, except travel reimbursed or sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education as defined by federal law; an academic teaching hospital; a medical center; or a research institute affiliated with a U.S. institution of higher education.

For travel requiring disclosure, the Investigator must disclose, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

For purposes of this policy, financial interests from foreign institutions of higher education and foreign governments are subject to disclosure when they meet the applicable criteria above.

Significant Financial Interest does not include:

- Salary, royalties, or other remuneration paid by RIPHI to the Investigator if the Investigator is currently employed or otherwise appointed by RIPHI, including intellectual property rights assigned to RIPHI and agreements to share royalties related to those rights;
- Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions made in those vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education; an academic teaching hospital; a medical center; or a research institute affiliated with a U.S. institution of higher education; and
- Income from service on advisory committees or review panels for those same U.S.-based entities.

4. Investigator Disclosure Requirements

Each Investigator must disclose to RIPHI all domestic and foreign SFIs that are related to the Investigator's Institutional Responsibilities.

Disclosure must include applicable SFIs held by the Investigator's spouse and dependent children.

Investigators must submit an SFI disclosure:

- No later than the time an application for NIH-funded research is submitted;
- At least annually during the period of an NIH-funded award; and
- Within 30 days of discovering or acquiring a new SFI.

Investigators must provide sufficient information for RIPHI to determine whether an SFI is related to NIH-funded research and whether it constitutes an FCOI.

Investigators are responsible for providing complete, accurate, and timely disclosures.

5. Investigator Training

Each Investigator participating in NIH-funded research must complete FCOI training:

- Before engaging in research related to an NIH-funded grant;
- At least once every four years thereafter;
- When RIPHI revises this policy in a manner that affects Investigator responsibilities;
- When an Investigator is new to RIPHI; and
- When RIPHI determines that an Investigator has failed to comply with this policy or an FCOI management plan.

RIPHI may use NIH training materials or other training resources that satisfy applicable federal requirements.

6. Institutional Review

RIPHI shall designate an Institutional Official or officials responsible for administering this policy, soliciting and reviewing Investigator disclosures, determining whether an SFI is related to NIH-funded research, and determining whether an FCOI exists.

An SFI is considered related to NIH-funded research when RIPHI reasonably determines that the SFI:

1. Could be affected by the NIH-funded research; or
2. Is held in an entity whose financial interest could be affected by the research.

An FCOI exists when RIPHI reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Prior to the expenditure of funds under an NIH-funded project, RIPHI's designated official shall review all applicable Investigator disclosures, determine whether any SFI is related to the NIH-funded research, determine whether an FCOI exists, and, when necessary, develop and implement an appropriate management plan.

7. New or Newly Disclosed Financial Interests

When an Investigator who is new to an ongoing NIH-funded project discloses an SFI, or when an existing Investigator discloses a new SFI, RIPHI shall review the disclosure within 60 days.

RIPHI shall determine whether the SFI is related to NIH-funded research and whether an FCOI exists. If an FCOI exists, RIPHI shall implement, at least on an interim basis, a management plan specifying the actions that have been and will be taken to manage the conflict.

The same review process shall apply when RIPHI identifies an SFI that was not disclosed in a timely manner or was otherwise not previously reviewed during an ongoing NIH-funded research project.

8. Management of Financial Conflicts of Interest

When RIPHI determines that an FCOI exists, RIPHI shall take appropriate action to manage the conflict and protect the objectivity of the NIH-funded research.

Depending on the nature of the conflict, a management plan may include:

- Public disclosure of the FCOI, including disclosure in publications or presentations;
- Disclosure of the FCOI directly to research participants when appropriate;
- Independent monitoring of the research;
- Modification of the research plan;
- Modification of the Investigator's role or responsibilities;
- Disqualification of the Investigator from all or a portion of the research;
- Reduction or elimination of the financial interest; or
- Severance of the relationship creating the conflict.

Management plans shall describe the Investigator's role in the research, the conditions imposed to manage the conflict, how those conditions protect the objectivity of the research, how compliance will be monitored, and any other information RIPHI determines appropriate.

The Investigator must agree to comply with the management plan. RIPHI shall monitor compliance with the management plan through completion of the applicable research project.

9. Reporting Financial Conflicts of Interest to NIH

RIPHI shall report identified FCOIs to NIH through the eRA Commons FCOI Module in accordance with federal requirements.

(401) 648.4700 www.odhpvd.org (833) 905.2260
7 Central St. Providence, RI 02907

For an FCOI identified before expenditure of funds under an NIH-funded project, RIPHI shall submit the required FCOI report before funds are expended.

For an Investigator who becomes newly involved in an ongoing project, or for a new or newly identified FCOI involving an existing Investigator, RIPHI shall submit the required report within 60 days of identifying the FCOI.

For each previously reported FCOI, RIPHI shall provide an annual update addressing the status of the FCOI and any changes to the management plan for the duration required by NIH.

FCOI reports shall include all information required by NIH, including information concerning the Investigator, the entity involved, the nature and value of the financial interest, the relationship between the financial interest and the NIH-funded research, and the key elements of RIPHI's management plan.

10. Retrospective Review and Mitigation

When RIPHI identifies an SFI that was not disclosed or reviewed in a timely manner, an FCOI that was not identified or managed in a timely manner, or an Investigator's failure to comply with an FCOI management plan, RIPHI shall determine whether a retrospective review is required.

When required, RIPHI shall complete and document a retrospective review within 120 days of determining that noncompliance occurred to determine whether the NIH-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting.

The retrospective review shall include, at minimum:

- The project number and title;
- The name of the project director/principal investigator;
- The name of the Investigator with the FCOI;
- The name of the entity associated with the FCOI;
- The reason for the retrospective review;
- The methodology used to conduct the review;
- The findings of the review; and

- The conclusions of the review.

If bias is identified, RIPHI shall promptly notify NIH and submit a mitigation report addressing the impact of the bias and the actions taken or planned to eliminate or mitigate its effects.

RIPHI shall update previously submitted FCOI reports when required based on the results of a retrospective review.

11. Noncompliance

Failure to comply with this policy, disclosure requirements, or an FCOI management plan may result in corrective or disciplinary action consistent with RIPHI policies and applicable law.

Possible actions may include additional training, modification or suspension of research responsibilities, restriction on the use of research funds, removal from an NIH-funded project, disciplinary action, or other measures RIPHI determines appropriate.

RIPHI shall promptly notify NIH when required regarding noncompliance and shall take appropriate corrective action.

If the U.S. Department of Health and Human Services determines that an NIH-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required, RIPHI shall require the Investigator to disclose the FCOI in each public presentation of the research results and request an addendum to previously published presentations as required by federal regulation.

12. Subrecipient Requirements

When RIPHI conducts NIH-funded research through a subrecipient, subcontractor, consortium member, or collaborator, RIPHI shall take reasonable steps to ensure that Investigators working for that entity comply with applicable FCOI requirements.

The written agreement between RIPHI and the subrecipient shall specify whether the subrecipient's Investigators will comply with:

1. The subrecipient's FCOI policy; or
2. RIPHI's FCOI policy.

If the subrecipient's policy applies, the subrecipient must certify that its policy complies with 42 CFR Part 50, Subpart F. The written agreement shall establish reporting deadlines that allow RIPHI to meet its reporting obligations to NIH.

If RIPHI's policy applies, the written agreement shall establish deadlines for subrecipient Investigators to submit disclosures to RIPHI in sufficient time for RIPHI to review, manage, and report any identified FCOIs within applicable federal deadlines.

13. Public Accessibility

RIPHI shall maintain this policy on its publicly accessible website and shall submit the policy to NIH through the eRA Commons Institution Profile Module as required by NIH. Additionally, this policy is included in RIPHI's "Employee Handbook," which is reviewed and signed by all RIPHI staff members on an annual basis.

Prior to the expenditure of NIH funds, RIPHI shall make information concerning identified FCOIs held by senior/key personnel publicly accessible either through its website or by providing a written response within five business days of a written request.

Information made publicly accessible shall include, at minimum, the information required by 42 CFR Part 50, Subpart F.

This policy shall be updated at least annually and within 60 days of identifying a new FCOI subject to public disclosure. Information shall remain available for at least three years from the date it was most recently updated.

14. Record Retention

RIPHI shall maintain records relating to:

- Investigator disclosures of financial interests;
- RIPHI's review of and response to those disclosures, regardless of whether an FCOI was identified;
- FCOI determinations and management plans;
- Investigator compliance with management plans;
- Reports submitted to NIH;
- Retrospective reviews and mitigation reports; and

- Other actions taken under this policy.

Records shall be maintained for at least three years from the date the final Federal Financial Report is submitted to NIH, or for any longer period required by applicable federal regulations, award terms, litigation holds, audits, or RIPHI's record-retention requirements.

15. Institutional Responsibilities

RIPHI shall maintain an up-to-date, written, and enforced administrative process for identifying and managing FCOIs.

RIPHI shall:

- Inform Investigators of this policy and their disclosure and training responsibilities;
- Solicit and review required SFI disclosures;
- Determine whether disclosed SFIs constitute FCOIs;
- Develop and monitor management plans when necessary;
- Submit required FCOI reports to NIH;
- Maintain required records;
- Make required FCOI information publicly accessible;
- Ensure appropriate compliance by subrecipients; and
- Make information concerning Investigator disclosures, institutional reviews, determinations, and FCOI management available to NIH promptly upon request.

16. Investigator Responsibilities

Each Investigator subject to this policy is responsible for:

- Understanding and complying with this policy;
- Completing required FCOI training;
- Disclosing all applicable domestic and foreign SFIs completely and on time;
- Updating disclosures when required;
- Providing additional information requested by RIPHI in connection with an FCOI review;

- Complying with any management plan established by RIPHI; and
- Cooperating with institutional reviews, retrospective reviews, monitoring, and reporting activities.