PHS FUNDED RESEARCH

FINANCIAL CONFLICT OF INTEREST POLICY

I. Policy

The ultimate goal of this policy is to protect the integrity and credibility of all activities related to research and to maintain the public's trust and confidence in Lovelace Respiratory Research Institute (LRRI) and its employees. This PHS Funded Research Financial Conflicts of Interest (FCOI) Policy addresses the responsibilities of safeguarding research objectivity and protecting human subjects and LRRI researchers who may be exposed to conflict of interest situations and enabling compliance with applicable laws and other regulatory requirements. Research activities occurring at LRRI must not be adversely affected by financial or other interests of persons involved in those activities.

LRRI recognizes the importance of the relationships between LRRI staff and other organizations and seeks to encourage such relationships. Very often these relationships can produce significant discoveries that may result in useful products or treatments. Productive external relationships with other organizations also can inspire new avenues of inquiry and provide opportunities to collaborate in new research. LRRI permits employees to engage in external activities, subject to certain oversights and limitations. Although such outside activities are often compatible with an employee's duties at LRRI, they may in some instances lead to conflicts of interests related to the employee's responsibilities at LRRI.

FCOI arising from an employee's external interests or activities can make it difficult for an employee to perform their LRRI duties impartially. Therefore, this policy is used to clarify the professional obligations of all employees of LRRI with respect to external activity that may give rise to FCOI.

II. Regulations

As defined by 42 CFR Part 50 Subpart F (Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought) and 45 CFR Part 94 (NIH – Financial Conflict of Interest Regulations). These regulations are mandated by the federal government and this policy is intended to comply with the requirements of the regulations.

III. Purpose

The regulations are intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under National Institutes of Health (NIH) grants, contracts or cooperative agreements will be free from any bias resulting from any FCOI.

IV. Scope

Compliance with Federal Regulations. All research activity undertaken at LRRI must be conducted in compliance with all relevant federal regulations.

Disclosure Obligation. LRRI staff must be aware of any circumstances or activities that can create either FCOI and/or relationships that might jeopardize the credibility of their work or damage their personal reputations or that of LRRI. FCOI can arise when an investigator's private financial interests come into conflict with their research responsibilities, thus raising the concerns about objectivity and/or improper gain.

FCOI are sometimes inevitable, and by their mere existence do not mean or imply any impropriety or wrongdoing on the part of the investigator or key personnel. Full disclosure and

transparency is always the best approach in avoiding any regulatory or legal consequences. Fully disclosing potential FCOI at the earliest possible time or as soon as you become aware of them will always provide the best protection for an investigator's interests.

Early disclosure is an important element in protecting an investigator's reputation and career from any potentially embarrassing or harmful allegations of inappropriate conduct. Therefore, investigators are strongly encouraged to disclose any situation that might conceivably be viewed as a FCOI or as a reportable Significant Financial Interest (SFI) and to voluntarily submit and disclose all known information rather than less information.

Therefore, prior to participating in a research activity, anyone having an SFI related to the research activity must report the interest to the FCOI Institutional Official (IO), who is responsible for reviewing the disclosure forms and then making the determination about whether a conflict actually exists. If a FCOI is found to exist, then the IO will develop and implement an adequate mitigation plan for the management of any conflict risks or concerns, communicating the conflict to appropriate stakeholders, and if applicable, submitting any of the necessary reports to the appropriate agency. FCOI must be reported using the FCOI Disclosure Form.

To whom does this policy apply? This policy applies to anyone who is working for LRRI and who may be receiving or has already received either a U.S. Public Health Service (PHS) or NIH grant, contracts or cooperative agreement for research. This includes the investigator and/or key personnel who are planning to participate in or who are already participating in research. Be aware that the term “investigator” has a broad definition and 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 research either funded by the NIH, or proposed to be funded, which may include, for example, collaborators or consultants.

What type of research activities are required to be disclosed? Research activities include any and all of the investigator's professional responsibilities performed on behalf of LRRI. This includes research, research consultation, teaching, professional practice, institutional committee memberships, and participation on panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs).

What is a Financial Conflict of Interest and how do I know if I have one? A FCOI arises when an investigator or you have a Significant Financial Interest (SFI) that could directly or significantly affect or influence your actions or decisions in the design, conduct, or reporting of NIH-funded research. If you’re not sure if you have an actual FCOI, ask the Director of Business Affairs. See Definition section below for greater clarification.

What constitutes a Significant Financial Interest (SFI) and how do I know if I have one? An SFI exists if any of the following circumstances exist for either the investigator, their spouse, or any dependent children, and it may reasonably appear to conflict or be related to the investigator’s institutional responsibilities, and for which the economic value or benefits of the SFI either equals or exceeds a total of $5,000 (Five Thousand Dollars) within a 12-month period. If you’re not sure if you have an SFI, ask the Director of Business Affairs. SFIs include income or any payment for services not otherwise identified as salary. Examples would include but not be limited to:

- Consulting fees, honoraria, paid authorship, or anything of economic value or benefit
- Equity interest and company stock, stock options, or other ownership interest

- Intellectual property rights and interests such as patents and copyrights determined upon receipt of income related to such rights and interests
- the occurrence of any reimbursed or sponsored travel
- Travel that is paid on behalf of the investigator and not reimbursed to the investigator

Note the disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulations.

When am I required to complete the FCOI Disclosure Form? You are required to either complete the FCOI Disclosure Form or update it when any of the following circumstances apply:

- **At Time of the Application:** Require that each investigator, including sub-recipient investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated IO at time of application.
- **Annually:** Require each Investigator, including the sub-recipient investigator, if applicable, to submit an updated disclosure of any existing SFI at least annually, in accordance with the specific time period prescribed by the Institute, during the period of the award.
- **Within 30 Days:** Require each investigator, including sub-recipient investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within 30 days of discovering or acquiring a new SFI.

Who at LRRI has the regulatory responsibility and authority to determine if there is a Financial Conflict of Interest? The Director of Business Affairs is the LRRI Institutional Official (IO) responsible for the FCOI Policy. LRRI is required by federal regulations to designate an IO who is responsible for soliciting and reviewing disclosure statements from each investigator who is planning to participate in or who is already participating in PHS or NIH funded research.

Training Requirements. All investigators, and subcontractors are required to participate in training and then to review and document their willingness to comply with this policy. A copy of this policy will be provided to all new investigators and then annual reminders will be sent to ensure compliance with the ongoing disclosure responsibilities. Training will also need to occur at least every 4 years and will be provided to investigators on any change in requirements or definitions.

Violations of this FCOI Policy. Intentional, reckless, or negligent violations, or any deceptive conduct or actions intended to avoid or evade the oversight provisions of this policy can and may result in legal, regulatory, and/or employment-related consequences, including but not limited to, suspension or termination of employment.

V. Other LRRI-Prohibited Financial Conflicts of Interest

Gratuities. No investigator may accept any gratuity or special favor from individuals or organizations with which LRRI is doing business or for which under the circumstances might reasonably be interpreted as an attempt to influence them in the conduct of their duties.

Participation in Business Negotiations. No investigator having an SFI in a commercial or non-profit organization outside of LRRI may participate in negotiating the terms and conditions of any agreement between LRRI and that organization on behalf of either party.

Participation in Administration of Agreements. No investigator having an SFI or a management position in a commercial or non-profit organization outside of LRRI may have primary responsibility for administering an agreement between LRRI and that organization on behalf of either party.

Clinical Trial Investigators. No one may participate as a Principal Investigator (PI) in a clinical trial sponsored by a start-up commercial or non-profit organization in which he or she has any equity or intellectual property interest, holds a management position, or serves on the organization's Board of Trustees.

Financial Interests in Competitors' and Competitive Products. Investigators will be considered as having a financial interest for the purposes of this policy if they have any interest of economic or monetary value in a business that produces a competing product that could reasonably appear to affect or to be affected by the particular research activity under consideration.

Clinical Trials of LRRI or LRRI Technology. No person shall participate in a clinical trial involving technologies licensed by LRRI if that person has a substantial equity interest in the licensee or intellectual property interest in the technology without a full conflict of interest review and implementation of a FCOI mitigation management plan. When LRRI has either a substantial equity interest in the licensee or an intellectual property interest in the technology, funding for clinical trials will not be accepted without a full conflict of interest review and a review of the mitigation management plan being implemented.

Conflicting Management Roles in Outside Organizations. No person may simultaneously serve in key management positions for both LRRI and an outside organization on the same research project. For purposes of this guideline, key management positions will include PI and any other role in which the person has the authority to make or recommend significant business, contractual, or financial decisions relating to the research project. In no event may an investigator act as PI for both LRRI and an organization contracting with LRRI with respect to a research project unless another LRRI employee, not in a direct reporting relationship to the conflicted investigator, has been designated by LRRI to be responsible for all business, contractual, and financial decisions relating to the outside organization.

VI. Definitions

Clinical Trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (such as drugs, treatments, devices, or new ways of using known drugs, treatments or devices).

Conflict of Commitment, which may also be called "conflict of effort" or "conflict of obligation," occurs when the time or effort that an employee devotes to external activities interferes with his or her LRRI responsibilities or when an employee makes inappropriate use of LRRI resources in the course of an external activity.

Conflict of Interest is a situation in which private or personal interests have the potential to conflict, compromise, or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised or influenced. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not the likelihood. A conflict of interest can arise naturally from an employee's engagement with the world outside of LRRI and the existence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognized, disclosed, and either eliminated or properly managed.

Disclosing the required information at the earliest possible time will afford the best protection of a person's interest. Conflicts of interest may take many forms. For the purposes of this policy, they will be addressed under two classifications:

1. **Financial Conflicts of Interest** (FCOI) (related to the performance of federal research under 42 CFR Part 50, Subpart F and/or 45 CFR Part 94) occur when an employee's obligations to LRRI, including research activities, could be compromised or influenced by his or her external activities or agreements, particularly financial agreements that provide research funding, other funding, or compensation. The regulations stipulate that outside work is reportable if representing compensation greater than a specified threshold or if representing a significant financial interest or management interest in a private enterprise. Ideally, an FCOI–related disclosure will be made by an employee prior to their acceptance of a qualifying outside work commitment and/or relationship. If the reporting threshold is not reasonably foreseeable in advance, disclosure must be made in the course of events as the relevant triggers are approached. LRRI policy requires a FCOI disclosure to the appropriate Institutional Official (IO) prior to submission of any proposal.
2. **General Conflicts of Interest** occur when an employee or immediate family member receives personal benefit from the employee's LRRI position in a manner which may inappropriately influence the employee's judgment, compromise the employee's ability to carry out their LRRI responsibilities, or damage the organization's integrity. It is the responsibility of each employee to identify and disclose potential conflicts of interest to their supervisor. Supervisors will work with the appropriate IO and other LRRI management members, as needed, to manage or resolve the conflict and create appropriate documentation.

External activity means involvement with any person, trust, organization, enterprise, government agency, or other entity that is not associated with or under the control of LRRI.

Human Subject refers to any living individual about whom the investigator conducting research obtains data through direct intervention or interaction, or identifiable private information.

Institutional Official (IO). The IO is the Director of Business Affairs. The IO may designate one or more delegates to perform specific tasks to ensure compliance with this policy.

Inventor is any person who has created intellectual property in which LRRI has any right or interest, including but not limited to patents, trademarks, copyrights, trade secrets, or know-how.

Investigator. Refers to the Principal Investigator, co-investigator(s), or any other person responsible for the design, conduct, or reporting of research funded by NIH or proposed for such funding, such as investigators working for sub-grantees, contractors, subcontractors, collaborators. The term "investigator" includes the investigator's spouse and dependent children.

IRB is the Institutional Review Board, also known as an independent ethics committee (IEC) or ethical review board (ERB). This committee has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.

Key Personnel 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 research funded by NIH or proposed for such funding.

Management Plan is a written plan for the management, reduction, or elimination of potential conflicts of interest relating to an individual's institutional responsibilities. Possible management of conflicts of interest may include, but are not limited to, public disclosure of the significant financial interest, monitoring of the research by independent reviewers, modification of research

plans, divestiture of the significant financial interest, and severance of the relationships that created the conflict.

Principal Investigator is the investigator who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.

Research is a systematic investigation designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social science research. The term encompasses basic and applied research and product development.

Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse, and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:

- Salary, royalties, or other payments for services such as consulting fees or honoraria, if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, meets or exceeds $5,000.
- Reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Note the exclusions to travel related disclosures that are listed in the section below.
- Equity interests such as stocks, stock options, or other ownership interests if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, meets or exceeds $5,000, or when the investigator (or the investigator's spouse, domestic partner, or dependent children) holds <u>any</u> equity interest (e.g., stock, stock option, or other ownership interest) in a non-publicly traded entity.
- Intellectual property rights such as patents, copyrights, and royalties from such rights.

Significant Financial Interest does <u>not</u> include the following:

- Salary, royalties, or other remuneration from LRRI to the investigator if he/she is currently employed or otherwise appointed by LRRI.
- Intellectual Property Rights assigned to the institution and agreements to share in royalties related to such rights.
- Any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization.
- 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.

- Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for 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.
- 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.

VII. Procedures

Responsibilities of Investigator and Key Personnel

Disclosure Requirements. It is the responsibility of the investigator or key personnel of a research project to identify and complete the FCOI Disclosure Form if they have an SFI requiring reporting under this policy. It is the responsibility of the investigator or key personnel to report any known FCOI for other investigators who anticipate participation or who are already participating in research when the FCOI has not already been reported.

It is the responsibility of the investigator or key personnel of a research project to; if governed by a mitigation management plan to ensure compliance with the plan and to provide an annual report (or more frequently, if required) directly to the FCOI Institutional Official.

SFI's must be reported by an investigator under the following circumstances:

- When a proposal for a research project is submitted to the LRRI Office of Research Contracts (ORC).
- To submit an updated disclosure of any existing SFI at least annually, in accordance with the specific time period prescribed by the Institute, during the period of the award.
- Within 30 days of discovering or acquiring a new SFI.
- When requested by the Institute.

On the submission of non-competitive continuations, PIs are required to certify that:

- There are no SFI changes since the original competitive application and the project is compliance with any and all management plans (if any) issued.
- Any SFI disclosures have been submitted to the FCOI Institutional Official, using the FCOI Disclosures Form.

The FCOI Disclosure Form and FCOI Annual Report are to be completed and submitted to the FCOI Institutional Official for disclosure of all significant financial interest and/or any financial conflict of interest.

Office of Research Contracts

It is the responsibility of the ORC to:

- Notify the FCOI Institutional Official of any SFI indicated on FCOI Disclosure Forms.
- Notify the FCOI Institutional Official of any indicated changes in SFI status on FCOI Disclosure Forms.

- Place a hold on all project accounts in which a report was made until notified by FCOI Institutional Official that the potential conflict was eliminated, reduced, or otherwise adequately managed.
- Obtain notification of any existing conflicts of interest identified by subcontractors and obtain written assurances from the subcontractors that the SFIs have been disclosed and managed.
- Notify FCOI Institutional Official of both subcontractor conflicting interests and subcontractor assurances.

Institutional Official (IO)

It is the responsibility of the Institutional Official to:

- Review LRRI FCOI Disclosure Forms and reports.
- Determine the terms, conditions, and restrictions, if any, that are required as part of a mitigation management plan.
- Provide the President/Chief Executive Officer (CEO), and Chief Financial Officer with notification of any management plans put into place.
- Report disposition of matters involving a report in accordance with federal requirements 42 CFR part 50 and 60 FR 35820 – 35823 July 11, 1995 and Aug 24, 2012.
- Retain records on reports for a period of no less than 3 years.
- Take actions as deemed reasonable to audit and monitor compliance with management plans.
- Report violations of this policy, including failure to make a required report of financial interests or failure to comply with the requirements of a management plan to the President/CEO of LRRI.

President/CEO (or designee)

Institute-appropriate sanctions or discipline for investigators or inventors violating this policy will be implemented by the President/CEO.

Ongoing Disclosure Responsibilities

Disclosure requirements apply for the duration of the research. Investigators must disclose any of the following that occur during the sponsored research within 30 days of discovery when:

- Any new SFI that could reasonably appear to have an effect on the research
- Any new situation that could call into question the investigator's professional commitments while performing the research or the investigator's primary responsibilities to LRRI
- Any material change occurs to a previously reported disclosure
- An investigator is added to the project and who has not previously submitted a disclosure form.

Mitigation Management Plan

The FCOI Institutional Official in consultation with the investigator will determine if a mitigation management plan is required and the specific terms, conditions, and restrictions that are required for the plan. The management plan will be communicated to the appropriate

stakeholders. Copies of the FCOI mitigation management plan also may be provided to the appropriate IRB office for review. Management plans will at a minimum include:

- Role and principal duties of the conflicted investigator in the research project
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance
- Other information as needed

The Management plan may include but not be limited to any of the following actions in order to mitigate, manage, monitor, audit, reduce, or eliminate any conflict of interest:

- Disclosing of the Significant Financial Interests (SFIs), including to the public, human subjects, researchers and other participants, publishers, and conference organizers
- Monitoring of the research by independent researchers and/or reviewers, unbiased individual, or committees
- Placing copies of research data with a neutral party
- Disqualifying specific individuals from participation in all or a portion of the research
- Requiring that the SFI be divested, restructured, or placed in blind trust
- Modifying or ending the relationships that create potential conflicts of interest
- Changing terms of agreement relating to the research
- Requiring that the investigator's participation in the recruitment or consent of subjects in human subject research be prohibited or restricted
- Requiring the exclusion from participation in any business transactions between LRRI and parties to agreements involving sponsored research or other business relationships

All investigators who are subject to a management plan must comply with reporting requirements and report annually or more frequently if so required by the management plan. These reports must be provided directly to the FCOI Institutional Official.

LRRI will take whatever actions are necessary to perform audits, monitor, and enforce the compliance requirements of management plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connections with such management plans.

Public Accessibility to FCOI Information

- LRRI's FCOI policy may be posted on the Institute's public website or made available to the general public when requested.
- Information about FCOIs of investigator and key personnel also may be posted on the Institute's public website or made available to the general public when requested.
- The information that will be provided to the public will include:
    - Investigator's name
    - Investigator's title and role with respect to the research project
    - Name of the entity in which the SFI is held

    - Nature of the SFI
    - Approximate dollar value of the SFI or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- This information will remain available for 3 years from the date the information is most recently updated.