



THE RYR-1 FOUNDATION INVESTIGATOR FINANCIAL CONFLICT OF INTEREST POLICY

INTRODUCTION

This Investigator Financial Conflict of Interest Policy is designed to foster public confidence in the integrity of The RYR-1 Foundation (the "**Institution**") and to implement the requirements of 42 CFR 50 Subpart F and 45 CFR 94 (the "**Requirements**"). Where there are substantive differences between this policy and the Requirements, the Requirements shall take precedence.

This policy applies to all Investigators of the Institution. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the Financial Conflict of Interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to the Institution's policies.

DEFINITIONS

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of clinical trials, drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator that is related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored Research.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of Financial Interests and Significant Financial Interests including those of the Investigator's Family related to the Investigator's Institutional Responsibilities. For the purposes of this policy, the Institutional Official is designated as Lindsay Goldberg.

Institutional Responsibilities means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as Research, teaching, clinical activities, administration, and Institutional, internal or external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS-sponsored Research or proposals for PHS-sponsored funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare

Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

CONFLICT OF INTEREST

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize Financial Conflict of Interests, and must respond appropriately when Financial Conflicts of Interest arise. To that end, this policy informs Investigators about situations that generate Financial Conflicts of Interest related to Research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of a Financial Conflict of Interest arises, an Investigator should discuss the situation with the Institutional Official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their Financial Interests to the Institution on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

- a) **Annual Disclosures.** Investigators must disclose to the Institution through the Institutional Officer on an annual basis their Financial Interests, including their Significant Financial Interests that are related to the Investigator's Institutional Responsibilities. All forms should be submitted to the Institutional Official by January 30th of each calendar year.
- b) **Ad hoc Disclosures.** In addition to the annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Financial Interests, including their Significant Financial Interests, to the Institution through the Institutional Official within 30 days of their initial appointment or employment.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

- c) **Travel.** Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest.

2) **REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL**

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the Financial Conflict of Interest which may include the reduction or elimination of the conflict, as appropriate.

Prior to entering into any PHS-sponsored projects or applications for PHS-sponsored funding, where an Investigator has a Significant Financial Interest, the Investigator shall either (1) certify to the Institutional Official that the Significant Financial Interest(s) disclosed on the previously submitted annual disclosure comprise all of the Investigator's current Significant Financial Interest(s) or (2) submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interest(s). The Institution will not submit a project or funding proposal unless the Investigator(s) have submitted such certifications or ad hoc disclosures.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored Research or funding. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the written management plan and sign the plan Prior to entering into PHS-sponsored projects or submitting applications for PHS-sponsored funding.

3) **CLINICAL TRIALS**

Review of Significant Financial Interests Related to Clinical Trials. Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

In the event of non-compliance with reporting and/or management of a Financial Conflict of Interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this policy, the Investigator must disclose any Financial Conflict of Interest in each public presentation of the results of the affected PHS-sponsored Research and request an addendum to previously published presentations so appropriate disclosure can be made.

4) **REPORTING TO PHS**

The Institutional Official will report Financial Conflicts of Interest or non-compliance with this policy to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest such that the prime awardee may fulfill their reporting obligations to the PHS. To the extent required by PHS regulations, the Institution shall submit a Mitigation Report in accordance with 42 CFR 50.605(a)(3)(iii).

5) **INVESTIGATOR NON-COMPLIANCE**

- a) **Disciplinary Action.** In the event of an Investigator's failure to comply with this policy, the Institutional Official may suspend all relevant activities of the Investigator or take other action as deemed appropriate until the matter is resolved, including disciplinary action against the Investigator.

The Institutional Official's decision to impose sanctions on an Investigator for failure to comply with this policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator and will notify the Investigator of the right to appeal the decision. The Institution will promptly notify PHS and the appropriate parties of the action taken or to be taken. If the funding for the project or Research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

- b) **Retrospective Review.** In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.

Documentation of the retrospective review shall include the project number, project title, name of Investigator, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going

forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the Institution will promptly notify the PHS and appropriate parties and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

6) **TRAINING**

Each Investigator must complete training on this policy, the Investigator's responsibilities regarding disclosures of Financial Conflicts of Interests, and the PHS regulations prior to engaging in Research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this policy is substantially amended in a manner that affects the requirements of Investigators, if the Investigator is new to the Institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their Institutional Responsibilities.

7) **RECORD RETENTION**

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

8) **CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be kept confidential. However, the Institution may be required to make such information available to PHS and/or HHS, to a requestor of information concerning any Financial Conflict of Interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9) **PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of a request for information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by any of the Institution's senior/key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

This policy shall be posted on the Institution's publicly accessible website.