

POLICY

Financial Conflict of Interest – Research		
Department: Operations		Drafted: May 15, 2015
Approved By:		Date Effective: July 1, 2015 Date Revised:

PURPOSE: Public Health Service revised its regulation in 2011. [Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought](#); 42 C.F.R. Part 50, Subpart F; 45 C.F.R. Part 94 (collectively, “PHS Regulation”). The revised regulation seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under Public Health Services (“PHS”) grants or cooperative agreements will be free from bias resulting from an Investigator’s financial conflicts of interest.

This Policy establishes requirements to make sure that NRHI is in full compliance with all pertinent regulatory requirements in applying for or receiving PHS funding from a grant or cooperative agreement. It is applicable to any PHS proposals submitted and/or awards received on or after August 24, 2012. To that end, this Policy sets forth the framework to identify, evaluate and manage financial conflicts of interest related to NRHI’s research activities to control their ability to create bias and to maintain integrity, credibility and respect for the work of NRHI’s staff.

POLICY: It is NRHI’s policy to follow all applicable federal regulations and guidelines. Compliance with the PHS regulation is a requirement to submit a proposal and accept an award of financial support from PHS for all related activities conducted under NRHI’s auspices, including that of NRHI’s sub-recipients.

Further, it is the policy of NRHI that an individual has an obligation to avoid any financial conflict of interest for which an approved management plan cannot or has not been developed and approved, through the FCOI Committee, and implemented by the individual and all involved parties.

A conflict of interest is considered to occur whenever an investigator, sub-investigator or key personnel (defined below) has an existing or potential financial interest that impairs or appears to impair their independence and objectivity in the design, conduct and reporting of research.

Investigators, sub-investigators and key personnel (defined below) should avoid conflicts of interest and the potential for conflicts through financial arrangements with entities that have a special interest in a research project or its findings.

NRHI has appointed the Vice President of Finance & Operations as the Institutional Official (defined below). All investigators, sub-investigators and key personnel (defined below) are required to submit a Financial Disclosure Form (Form 1) to the Vice President of Finance & Operations at the time of initial review of the research, annually thereafter and within 30 days of discovering or acquiring a new financial interest.

This policy and its procedures apply to all individuals who meet the federal definition of Investigator (defined below). Investigator may include principal investigators, project directors, NRHI consultants,

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external collaborators and sub-recipients.

DEFINITIONS:

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

Excluded payer means a Federal, state or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

Family member means the Investigator's spouse or dependent children.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the PHS-funded Research.

FCOI Committee means a committee composed of the Senior Director of CHT, Deputy Director, Senior Director of CHN and Senior Project & Operations Director. If any one of the FCOI Committee members is the Investigator at issue, that person shall be recused from being part of the FCOI Committee.

FCOI Report means NRHI's report of a financial conflict of interest required by law or otherwise by agreement to be made to a research sponsor or other oversight agency.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS research funding.

Institutional Official (IO) is the person designated by the Institution who is responsible for the review of all Financial Conflict of Interest Disclosures and the determinations of whether or not a conflict exists. The IO is responsible for the reporting of FCOI to all agencies that follow the FCOI guidelines.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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 research funded by the PHS (e.g., NIH/CDC), or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of Research will be free from bias.

Outside Organization means any organization other than NRHI or Excluded Payer.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any

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components of the PHS to which the authority involved may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health, Agency for Healthcare Research and Quality (AHRQ), 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, and Substance Abuse and Mental Health Services Administration.

PHS Awarding Component means the organizational unit of the PHS that funds the Research.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. It includes basic and applied research (e.g., a published article, book or book chapter) and any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the funding agency by the Institution under the regulation.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator (or the Investigator's Family Member) that reasonably appears to relate to the Investigator's Institutional Responsibilities:

- 1) 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 the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria); equity interests includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- 2) With regard to any non-publicly traded entity, a significant financial interest exists if the aggregated value of any remuneration received from the entity, in the twelve months preceding the disclosure, exceeds \$5,000, or when the Investigator (or Family Member) holds any equity interest (e.g. stock, stock option or other ownership interest);
- 3) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income by the Investigator related to such rights and interests;
- 4) Any Fiduciary Role in an Outside Organization; and
- 5) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, travel that 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 the Investigator's Institutional Responsibilities, except this disclosure requirement does not apply to travel that is reimbursed or sponsored by an Excluded Payer. At minimum, this disclosure requirement must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official may request other information about the trip as necessary to evaluate whether the travel may constitute a FCOI with the

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PHS-funded research.

A Financial Interest is related to an Investigator's Institutional Responsibilities if, for example, it arises from extramural activities that derive from the Investigator's professional standing or that are within that Investigator's expertise in his or her professional field(s) of discipline, such as consulting, serving on a scientific advisory board, providing continuing professional education services, or serving as an expert witness for an Outside Organization that, to the best of the Investigator's knowledge conducts or seeks to conduct business related to the Investigator's field of discipline. Further, equity in, or serving in a Fiduciary Role for, an Outside Organization that, to the best of the Investigator's knowledge, conducts or seeks to conduct business related to the Investigator's field of discipline, is related to the Investigator's Institutional Responsibilities.

SFI does not include:

- salary, royalties or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- intellectual property rights assigned to NRHI and agreements to share in royalties related to such rights;
- 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 an Excluded Payer; or
- income from service on advisory committees or review panels for an Excluded Payer.

INSTITUTIONAL RESPONSIBILITIES

The requirements that the regulation imposes on Institutions are outlined below.

1. Create and maintain an up-to-date written and enforced policy that complies with the PHS regulation.
2. Make the Institution's FCOI policy publicly available via a publicly accessible web site or make the written policy available to any requestor within five business days of a request if the Institution does not have any current presence on a publicly accessible web site. If, however the Institution acquires a presence on a publicly accessible web site during the time of the PHS award, the requirement to post the information on that web site will apply within 30 calendar days.
3. Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and of the PHS regulation.
4. Require each Investigator to complete training on the Institution's policy, the Investigator's responsibilities to disclose SFIs and of the regulation before engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - a. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - b. An Investigator is new to an Institution; or
 - c. An Institution finds that an Investigator is not in compliance with the Institution's financial

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conflict of interest policy or management plan.

5. Designate an institutional official(s) to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.
6. Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
7. Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of Significant Financial Interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph A.6. of this section, or in a subsequent disclosure of Significant Financial Interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest).
8. Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of Significant Financial Interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.
9. Provide guidelines consistent with 42 C.F.R. Part 50, Subpart F for the designated institutional official(s) to determine whether an Investigator's Significant Financial Interest is related to PHS-funded research and, if so related, whether the Significant Financial Interest is a FCOI. An Investigator's Significant Financial Interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the Significant Financial Interest: could be affected by the PHS-funded research; or is in an entity whose Financial Interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a Significant Financial Interest is related to the PHS-funded research. A FCOI exists when the Institution, through its designated official(s), reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
10. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to 45 C.F.R. § 94.4(c). Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to 42 C.F.R. §50.605(a).
11. Complete and document a retrospective review if necessary and, if bias is found, develop and submit a mitigation report.
12. Provide initial and annual (*i.e.*, ongoing) FCOI reports to the PHS as required through the eRA Commons FCOI Module.
13. Make available information concerning identified FCOIs held by Senior/Key Personnel publicly accessible consistent with the regulation and maintain public accessibility of the information for

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three years from the date the information was most recently updated. Make such information available before the expenditure of funds and update information at least annually and within 60 days of a newly identified FCOI.

14. Maintain records relating to all Investigator disclosures of Financial Interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 C.F.R. §74.53(b) and §92.42 (b) for different situations.
15. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
16. Agree to make information available promptly upon request to the PHS to any Investigator disclosure of Financial Interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a FCOI.
17. Responsibilities **Related to Subrecipients**
 - a. If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:
 1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators. Generally, NRHI will require that the subrecipient have and comply with its own FCOI policy and will apply the NRHI policy only in exceptional circumstances.
 - i. If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with 45 C.F.R. Part 94. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution;
 - ii. Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;
 - iii. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

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- iv. In all cases, the awardee Institution is responsible for reporting all identified FCOIs for subrecipient Investigators to the PHS through the eRA Commons FCOI Module.
 2. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with 42 C.F.R. Part 50, Subpart F, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- 18.** Certify, in each application for funding to which 42 C.F.R. Part 50, Subpart F applies, that the Institution:
- a. Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the PHS;
 - b. Shall promote and enforce Investigator compliance with 42 C.F.R. Part 50, Subpart F requirements, including those pertaining to disclosure of Significant Financial Interests;
 - c. Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with 42 C.F.R. Part 50, Subpart F;
 - d. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of Financial Interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a FCOI.
 - e. The Institution shall fully comply with the requirements of the PHS regulation.

PROCEDURES:

A. Investigator's Duty to Disclose Significant Financial Interests

1. No later than the time of application for PHS Research each Investigator must submit to the Institutional Official a disclosure of the Investigator's Significant Financial Interests (SFI) (and those of Family Members) and such other information as the Institutional official may require. This disclosure must be updated at the time of submission of a proposal for sponsored Research,¹ upon submission of a protocol, upon being added (in a capacity that meets the definition of Investigator) to an ongoing Research project, and also within 30 days of the Investigator's discovering or acquiring a new SFI. The required disclosures shall be made on the FCOI Disclosure Form attached to this Policy as Form 1. In addition to the disclosure of SFIs, the Investigator must provide requested information to assist in the assessment of whether any of the Investigator's SFIs are related to the Investigator's Research. For all Research projects, the PD/PI also shall be responsible to identify all Senior/Key Personnel who also are Investigators, as they become known and to report their identity within 10 days thereafter.
2. Each Investigator who is participating in the PHS-funded Research must submit an updated disclosure form at least annually, in accordance with the specific time period prescribed by

¹This includes proposals to transfer existing awards from another institution in connection with the commencement of an Investigator's employment by NRHI.

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NRHI, during the period of award. That disclosure shall include any information that was not disclosed initially to the Institution or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS -funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

3. Each Investigator who is participating in the PHS -funded research must submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (e.g., through purchase marriage, or inheritance) a new significant financial interest.
4. **Disclosure of travel:** Investigators who are funded or proposed to be funded by the PHS or other sponsor designated from time to time by NRHI, also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, travel that 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 the Investigator's Institutional responsibilities, other than travel reimbursed or sponsored by an *Excluded payer*. Travel disclosures must include the purpose of the trip, the identity of the trip's sponsor or organizer, the trip's origin and destination, and the duration of the trip. In addition, NRHI or the Institutional Official may request other information about the trip as necessary to evaluate whether the travel may constitute a FCOI.

B. Assessment of Disclosures

1. **Review by Institutional Official:** The Institutional Official shall review disclosures of SFIs and, where applicable, travel, and the Investigator's assessment of relatedness of SFIs to the Research in which the Investigator engages or proposes to engage. The Institutional Official shall review the disclosures and reasonably determine whether any of the disclosed SFIs or travel payments could be affected by the Research or are in an Entity whose Financial Interest could be affected by the Research. The determination of relatedness to the Research will be made based on both the Investigator's assessment of relatedness and on other facts reasonably deemed relevant by the Institutional Official or the FCOI Committee.
2. **Review by the FCOI Committee:** The FCOI Committee is responsible for the ultimate determination regarding whether a related SFI constitutes a FCOI and, if so, whether the FCOI is amendable to management and the management plan. If the Institutional Official determines that one or more disclosed SFIs or travel relate to the Research, the Institutional Official shall direct the Investigator to submit information regarding those related SFIs to the FCOI Committee, using such means of disclosure as may be prescribed from time to time. The FCOI Committee shall determine whether an SFI constitutes a FCOI, whether the FCOI is manageable and, if so, the management plan. The primary scope of inquiry of the FCOI Committee is to review matters involving SFIs and their potential to affect the objectivity of specific Research.

The determinations of the FCOI Committee require approval by a majority of the members present during the meeting. A member may be present at the meeting either in person or by electronic means, such as telephone or internet conferencing. A quorum of three members present is required for a meeting. Any tie vote by the FCOI Committee shall be broken by the

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Institutional Official.

In general, the following types of *SFIs* related to Research will be reviewed by the FCOI Committee, as they are likely to constitute a FCOI, unless there are factors that would reasonably prevent any direct or significant effect on the design, conduct, or reporting of the *Research*:

- a. Equity in a privately held Outside Organization that is actively conducting or seeking to conduct business related to the Research;
- b. Equity with a value greater than \$50,000 or greater than 5% ownership in a publicly traded Outside Organization that is actively conducting or seeking to conduct business related to the Research;
- c. Payments greater than \$25,000 in the preceding 12 months from an Outside Organization;
- d. Fiduciary Role on behalf of an Outside Organization that is actively conducting or seeking to conduct business related to the Research; or
- e. Intellectual property interest (not assigned to NRHI or an *Excluded payer*) if any income has been received from such intellectual property interest in the preceding 12 months.

The Institutional Official also may choose to submit for FCOI Committee review other types of *SFIs* not listed above or instances where an Investigator has more than one type of *SFI* related to the Research.

Before commencement of a Research project, review and assessment of FCOIs shall be conducted within the timeframes required by law or otherwise by agreement with the sponsor and, where applicable, shall be concluded before the expenditure of funds from the sponsor. During an ongoing Research project, should an Investigator who is new to the project disclose an *SFI* or should a current Investigator disclose a new *SFI*, the disclosure will be reviewed in the manner described above to determine whether the *SFI* relates to the Research and constitutes a FCOI.

C. Determination and Management of FCOI

A *SFI* may be found by the FCOI Committee to constitute a FCOI and may be subjected to a requirement that the FCOI be managed (including elimination of the Financial Interest, where appropriate) as a condition to the Investigator's participation in the Research to which it is related. The determination of whether a FCOI is manageable without elimination of the Financial interest should take into account relevant factors such as the nature and design of the Research; the magnitude and nature of the Financial Interest; the extent to which the Financial Interest could be influenced by the Research; the uniqueness of the Investigator's position with respect to the study (*e.g.*, whether safety or other factors will be diminished if the Investigator does not participate); and whether the interest is amenable to management.

1. **Management plan:** Where appropriate, a plan to manage the FCOI may be developed and recommended to the FCOI Committee. The FCOI Committee will have the authority to accept, modify, or reject the recommendations. The Institutional Official will communicate the findings and elements of the management plan to the Investigator and other NRHI personnel as appropriate. The Investigator will be granted the opportunity to review the

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management plan and must acknowledge in writing his or her acceptance of the obligation to abide by the plan.

Management Plans shall consist of measures that in the reasonable judgment of the Institutional Official will reduce, eliminate, or manage the effects of the FCOI. In developing a Management Plan, the Institutional Official may conduct factual inquiries and consult with and receive recommendations from such persons as the Institutional Official deems necessary and appropriate. The terms of a Management Plan shall be consistent with all legal and regulatory requirements, the requirements of this Policy, and may include one or more of the following:

- a. Disclosure of FCOIs, including to the public, researchers and other participants, publishers, and conference organizers;
 - b. Monitoring or oversight of Research by independent co-researchers, reviewers, disinterested individuals, or committees;
 - c. Maintaining copies of Research data with a neutral party;
 - d. Restricting participation in activity affecting or affected by a Research project;
 - e. Requiring that the SFI creating the FCOI be divested, restructured, or placed in a blind trust;
 - f. Modification or severance of relationships that create or are likely to create FCOI's;
 - g. Modifying the terms of written agreements relating to the Research;
 - h. Reduction in NRHI appointment;
 - i. Requiring that the Investigator not participate in any business transactions between the NRHI and parties to agreements involving sponsored Research.
- 2. Reconsideration:** If the Investigator objects to the terms of the management plan, the Investigator may submit promptly² to the FCOI Committee a written request for reconsideration, specifying the basis for the objection. The FCOI Committee also has the option to consult with the relevant NRHI officials. If the Investigator is not satisfied with the FCOI Committee's decision after such reconsideration, the Investigator may appeal to the CEO, whose determination is final.
- 3. Reporting:** Once the management plan has been finalized, the Institutional Official will prepare, if applicable, FCOI Reports required to be submitted to the research sponsor or oversight agency. The FCOI Reports shall contain information required by law or otherwise by the sponsor. The PHS regulation requires that such reports be made prior to the expenditure of funds, within 60 days of identifying a new FCOI for an existing Investigator or appointing a new Investigator with a FCOI to the Research project, at least annually and in

² The request for reconsideration must be made with sufficient time to allow NRHI to respond to the objection and comply in a timely manner with reporting requirements under applicable law.

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conjunction with progress reports or renewals, or when necessary to update a previously submitted report. The Investigator should be aware that information pertaining to FCOIs may be disclosed to sponsors or oversight agencies and, in some cases, to the public and may contain such details as the value and nature of the Financial Interest and elements of the management plan.

4. **Monitoring:** Establishment of a management plan also initiates responsibility for monitoring compliance with the plan until the completion of the Research project. As part of finalizing the management plan, the Institutional Official will establish an ongoing monitoring program to ensure compliance with requirements of the management plan.
5. **Unmanageable:** If the FCOI Committee concludes that a FCOI cannot be reduced, eliminated or managed, the Research project will not be allowed to proceed.

D. Investigator Obligation to Complete Training and Other Responsibilities

As a condition of applying for PHS-funded grants, awards or other funds subject to the regulations outlined in this policy, Investigators are responsible for and required to:

1. Attend NRHI provided or other required training on the regulations and their obligations under the regulations before engaging in Research at NRHI, and at least every four years thereafter;
2. Report all SFIs to the Institutional Official in accordance with the procedures set forth in this Policy;
3. Participate in and comply with any NRHI Financial Conflict of Interest Management Plan, including any retrospective review and/or mitigation plan;
4. Advise the Institutional Official with any sub-recipients or sub-awardees if the Investigator is the primary Investigator.

With regard to training, Investigators new to NRHI shall undergo training promptly after commencement of employment. In addition, each Investigator must undergo training within a reasonable period of time following any substantive change to this Policy that affects the requirements for Investigators, and must be retrained if it is determined that the Investigator has not complied with this Policy or with a management plan related to his or her activities. Training shall include a description of this Policy, the Investigator's disclosure responsibilities, an overview of the relevant Public Health Service regulation, and such other topics as the Institutional Official shall determine from time to time.

E. Investigator's General Obligation to Cooperate

The Investigator is required to cooperate fully with NRHI in all aspects of the administration of this Policy. Among other things, this includes providing all information as required to allow NRHI to understand and assess the Investigator's disclosure of SFI and the relatedness of the SFI to the Investigator's Research, assisting in the conduct of retrospective reviews where appropriate, and responding promptly and appropriately to implementation and monitoring of management and mitigation plans or corrective action.

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F. Public Accessibility

1. This Policy will be made available to the public via posting on NRHI's website at www.nrhi.org/FCOI_Policy.
2. In addition, to the extent required by law or otherwise by the terms and conditions of a Research award or as otherwise determined by the Institutional Official, NRHI will make available to the public certain information regarding FCOIs of Senior/key Personnel affiliated with the NRHI (and to the extent reported to NRHI, Senior/key Personnel at other organizations). In response to a written request submitted to NRHI for information related to FCOIs held at the time of the request by Senior/key Personnel of the particular Research project specified in the request, NRHI will, within five business days, provide as to Senior/key Personnel with FCOI related to such project: the Investigator's title and role with respect to the Research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate value of the Financial Interest reported in ranges (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to reasonable measures of fair market value.
3. The written request to NRHI must identify the project in sufficient detail to permit identification of the specific grant or contract.³
4. In lieu of response to individual requests as described above, the Institutional Official may in the future determine to employ postings on NRHI's website as the means of communication of information regarding FCOIs of Senior/key Personnel to the public. In the event that the website is used for that purpose, the website will contain the information described above and shall be updated with the frequency and maintained for the periods required by law.

G. Response to Non-compliance

1. **Review of untimely disclosures:** Should NRHI identify an SFI that, for any reason, was not disclosed by an Investigator within the required timeline or was not previously reviewed by NRHI during an ongoing Research project, the Institutional Official and NRHI will, within 60 days where required by law or by the terms of the Research award and in any event promptly as the circumstances allow, perform their respective responsibilities to review the SFI, determine whether it is related to the Research project, and determine whether a FCOI exists. If the Institutional official determines that the SFI constitutes a FCOI, NRHI shall implement a management plan describing the actions that have been and will be taken to manage the FCOI.
2. **Retrospective review and mitigation:**
 - a. In addition, if a FCOI (including FCOIs of subrecipients) is not identified or managed within the designated timeframe for any reason, where required by law or by the terms of the Research award or otherwise as may be appropriate in the view of the Institutional Official or NRHI, NRHI shall direct the Institutional Official (or subrecipient, as applicable)

³ Requests must be submitted in writing to the Vice President of Finance and Operations, Attention FCOI Request Department, 217 Commercial Street, Suite 500, Portland, ME 04101.

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to conduct in consultation with NRHI a retrospective review of the Investigator's activities and the Research project to determine whether any portion of the Research conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such Research.

- b. This retrospective review shall be completed within 120 days of the determination of non-compliance where required by law or by the terms of the Research award and in any event promptly as the circumstances allow.
- c. Documentation of a required retrospective review will include: the project number; project title; project director/principal investigator or contract project director/principal investigator; name of the Investigator with the FCOI; name of the entity with which the Investigator has a FCOI; the reason(s) for conducting the retrospective review; detailed description of the methodology used for the retrospective review; and the findings and conclusions of the review.
- d. As appropriate, NRHI will provide an updated FCOI Report, specifying actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review finds bias related to the Research project, NRHI will notify the research sponsor as appropriate. As required by law or agreement or as otherwise appropriate, this notification shall include a mitigation report including the key elements documented in the retrospective review above, a description of the impact of the bias on the Research project, and NRHI's plan for eliminating or mitigating the effect of the bias.

3. **Sanctions for violation:** If it is suspected that an Investigator has violated this policy, the Institutional Official, in consultation with the FCOI Committee and other administrative officials of NRHI, will make appropriate inquiry regarding the matter. If after such inquiry a violation is found, suitable corrective action may be taken. The Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action that the Institutional Official deems appropriate is implemented. Such action also may include those provided in the Employee Handbook, including termination.

If NRHI determines that an Investigator has failed to comply with this policy or a FCOI management plan and that the non-compliance appears to have biased the design, conduct, or reporting of the Research, NRHI shall promptly notify the research sponsor as required by law or agreement or as otherwise appropriate, of the corrective action taken or to be taken. Among other actions, NRHI may require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.

H. Responsibilities for Research Subrecipients

If required under the terms and conditions of a sponsored Research project, NRHI will require any written subaward agreement with any organization to include terms establishing the applicable FCOI policy governing the subrecipient's work, whether it is the NRHI policy or the policy of the subrecipient institution. The subrecipient will be required to provide certification that its policy is established in accord with sponsor requirements or, if unable to provide such certification, the NRHI policy will be applicable to all subrecipient Investigators. As a rule, NRHI will require subrecipient

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institutions to maintain and administer their own FCOI policies and will only in exceptional circumstances assume primary responsibility for directly soliciting and reviewing subrecipient personnel disclosures that enable NRHI to directly identify and manage identified FCOIs from the SFI disclosures of subrecipient personnel. In addition, the written subaward agreement will establish timelines and information requirements that will allow sufficient time for NRHI to evaluate, as applicable, subrecipient disclosures or subrecipient FCOI Reports in order for NRHI to meet any applicable sponsor reporting requirements.

I. Record Retention

In general, records related to the identification, evaluation and response to FCOI in Research shall be retained for three years following the date that the final Research expenditure report has been submitted to the research sponsor or for a longer period when specified by applicable governmental⁴ or NRHI requirements. If any litigation, claim, financial management review or audit is started before the three-year expires, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

J. Oversight by the Institutional Official

The Institutional Official, with the assistance of the FCOI Committee, is responsible for:

- communicating the expectations of NRHI's FCOI policy to the research community;
- providing access to appropriate FCOI training;
- designating tools and procedures for Investigator disclosure of SFIs;
- creating policies and guidelines for the determination of whether an FCOI exists;
- developing processes for the review of SFI disclosures, the evaluation of FCOIs, and the development and monitoring of management plans;
- establishing a process for providing FCOI Reports to the research sponsor or other oversight agencies as appropriate;
- implementing a procedure to provide required notification to the research sponsor if bias is found in the design, conduct, or reporting of Research and to submit any required mitigation plan to the sponsor;
- establishing a procedure for notifying research sponsors of non-compliance with this policy as appropriate;
- establishing procedures for the maintenance of FCOI-related records in accordance with NRHI and Federal record retention guidelines;
- establishing appropriate enforcement mechanisms, including actions to promote Investigator compliance;
- establishing procedures to implement that subrecipient agreements specify the use of NRHI or subrecipient FCOI policies;

⁴ Including where applicable, 45 C.F.R. 74.53(b) and 92.42, and 48 C.F.R. part 4, subpart 4.7 (all relating to record retention).

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- making this policy publicly accessible; and
- establishing a process for making information related to FCOIs held by Senior/key Personnel publicly available, where required, in the applicable timeframes.

These responsibilities may be delegated to other NRHI or, in consultation with the applicable officials as necessary and appropriate to promote adherence with this policy and applicable sponsor guidelines.

ADDITIONAL GUIDELINES:

The guidelines outlined below are adopted for use in the administration and application of this Policy, subject to such exceptions as the Institutional Official deems appropriate.

- A. Participation in Business Negotiations.** No NRHI employee having a FCOI related to a commercial or non-profit organization outside NRHI may participate in negotiating the terms and conditions of any agreement between NRHI and that organization.
- B. Participation in Administration of Agreements.** No NRHI employee having a FCOI related to or a management position in an Entity may have primary responsibility for administering an agreement between NRHI and that Entity.
- C. Availability of Research Data.** All data and results arising from Research in which an Investigator has a FCOI subject to a Management Plan under this Policy shall be available for disinterested scientific review.
- D. Outside Work.** Investigators receiving Compensation from an Entity must ensure that no services performed as part of outside work duplicate any work performed on behalf of the NRHI while participating in Research and that prior approval for such outside work is obtained.
- E. Performance of NRHI Obligations.** Any Investigator receiving Compensation from an Entity must ensure that no outside work activity is inconsistent with the obligations of the Investigator to NRHI.
- F. Disclosure of Interests.** All Investigators having a FCOI must disclose the nature of the Financial Interest in connection with scholarly publication or presentation of the results of the Research.
- G. Financial Interests in Competitors and Competitive Products.** For purposes of this Policy, a Financial Interest in a business that produces a competing product that could reasonably appear to affect or be affected by a particular Research project shall be deemed to be related to the Research project.
- H. Data Production and Analysis.** Investigators having a FCOI shall not perform primary data analysis or production of data involving subjective scoring or similar methods of obtain data unless there is a clear and convincing indication that the design of the Research and its analysis would provide no opportunity for bias.
- I. Conflicting Management Roles in Outside Organizations.** No person may simultaneously serve in key management positions for both NRHI and an Entity on the same Research project. For purposes of this guideline, key management positions shall include Principal Investigator and any other role in which the person has the authority to make or recommend significant business, contractual, or financial decisions on behalf of NRHI relating to the Research project. In no event may any Investigator act as Principal Investigator for both NRHI and an Entity contracting with

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NRHI with respect to a Research project unless another Investigator, not in a direct reporting relationship to the conflicted Investigator, has been designated by NRHI to be responsible for all business, contractual, and financial decisions relating to the outside organization.

- J. Some factors to consider to determine whether a FCOI exists include:
1. The degree to which there is a relationship between the SFI and the Research;
 2. The likelihood of influence;
 3. How the entity or its products are involved in the Research;
 4. Whether the interest is in a separate branch of a diversified entity;
 5. The Investigator's role on the project; and
 6. Any safeguards that are built into the design.

REGULATORY AUTHORITY: 42 C.F.R. Part 50, Subpart F
45 C.F.R. Part 94

RELEVANT FORMS: Form 1 – FCOI Disclosure Form

Form 2 – Institutional Subrecipient FCOI Disclosure Form

Form 3 – Independent Contractor Subrecipient FCOI Disclosure Form

TRAINING SLIDES

FORM 1 - FCOI DISCLOSURE FORM

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 research funded, or proposed for funding, by certain Federal Agencies. Typically this will include the Principal Investigators and co-Investigators, sub-recipients, consultants and collaborators. For the purpose of this disclosure requirement, the term “investigator” includes the investigator’s spouse and dependent children.

Investigators are responsible to:

1. Read NRHI’s FCOI Policy: <http://nrhi.org>
2. Read the National Institute of Health (“NIH”) Regulations and Code of Federal Regulations (“CFR”) on FCOI.
 - a. NIH Financial Conflict of Interest Overview: <http://grants.nih.gov/grants/policy/coi/>
 - b. Federal Register Notice for 45 CFR Part 50, Subpart F and 45 CFR Part 94: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
 - c. FCOI Frequently Asked Questions: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
3. Complete NRHI’s training on FCOI prior to completing this form. For training sessions, contact Michael Wilson at mwilson@nrhi.org.

INITIAL Disclosure UPDATE ANNUAL

INVESTIGATOR INFORMATION

Investigator Name: _____

Department/Company: _____

Project Role PD/PI Senior/Key Personnel Consultant Other

Project lead PD/PI Project Period

Project Title: _____

Proposed Sponsor: _____

DISCLOSURE OF SIGNIFICANT INTEREST

As the Investigator of a PHS funded research grant, cooperative agreement or contract you are required to disclose any Significant Financial Interest (“SFI”) (including SFIs of the Investigator’s spouse and dependent children) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research pursuant to 42 CFR 50. 603 and/or 45 CFR 94.3. One or more of the following interests would warrant disclosure of a SFI:

- Remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary; equity interest includes stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000 or any equity interest in such entity.
- Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests.
- Any reimbursed or sponsored travel (*i.e.*, travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) expenses.

You do not have to disclose:

- salary, royalties or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

- intellectual property rights assigned to NRHI and agreements to share in royalties related to such rights;
- 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 an Excluded Payer; or
- income from service on advisory committees or review panels for an Excluded Payer.

Excluded payer means a Federal, state or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

PLEASE CHECK ONE OF THE FOLLOWING:

I have NO significant financial interests to disclose which relate to my institutional responsibilities. (If you are NOT disclosing any Significant Financial Interest, please read and sign the “Investigator Certification” on page 3).

OR

I am disclosing Significant Financial Interest(s) as defined under federal regulation 42 CFR 50.603; 45 CFR 94.3 (and those of my spouse and dependent children), which relate to my institutional responsibilities. (If YES, you are disclosing Significant Financial Interest(s), please answer the subsequent questions followed by reading and signing the “Investigator Certification” on page 3).

Name and address of Entity (corporation, partnership, private practice, non-publicly traded entities, etc.):

Principal type of business: Value of the SFI: \$

How does the SFI relate to PHS-funded research? _____

- Did you (or your spouse or dependent children) receive any remuneration from any publicly traded 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**, exceed \$5,000? Yes No
- Did you receive any remuneration from any non-publicly traded entity in the twelve months preceding the disclosure,* **when aggregated**, exceed \$5,000? Or did you (or your spouse or dependent children) hold any equity interest in any non-publicly traded company? Yes No

*Exclusions -- excluded from income disclosure: NOT required to disclose 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. NOT required to disclose 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 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- Do you have income from an interest in any intellectual property rights impacted by the project? Yes No
 - In the last 12 months, did you receive reimbursed or sponsored travel from the entity**? Yes No
- If “Yes,” please provide the following trip details:

1. Purpose of trip:
2. Sponsor/Organizer:
3. Destination:
4. Duration:
5. Approximate monetary value:

**Exclusions -- excluded from travel disclosure: NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. NRHI will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

INVESTIGATOR CERTIFICATION

- I have read and understand the NRHI FCOI Policy.
- To the best of my knowledge, I have made all required financial disclosures.
- I agree to complete the FCOI training prior to engaging in research related to any PHS/NIH-funded grant or contract and anytime thereafter, and, immediately upon other events, as defined NRHI’s FCOI Policy.
- If the proposed project is funded by PHS/NIH, I agree, for the duration of the project, to update this disclosure either on an annual basis, or within 30 days if new reportable SFI(s) are obtained (such as through purchase, marriage or inheritance, for example).
- I agree to provide additional details needed by NRHI to meet NIH’s institutional filing, annual reporting and other requirements, and to cooperate in and comply with the development of a Management Plan to address any actual or potential conflict of interest identified via this Disclosure.
- If I participate in a project involving subrecipient organizations, I agree to assist NRHI in obtaining required disclosures in a timely manner from all subrecipient Investigators, and to assist NRHI, if requested, to manage any FCOIs of a subrecipient Investigator to assure compliance with the applicable regulations.
- I agree to comply with any retrospective reviews, conditions or restrictions imposed by NRHI to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Check if applicable: **CERTIFICATION BY PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR:**
The following people (or roles) meet the definition of Investigator for the above project, and I certify that they all will comply with the disclosure requirements of the NRHI FCOI Policy:

Signed: _____

Date: _____

CERTIFICATION BY INSTITUTIONAL OFFICIAL

- No financial conflict of interest appears to exist.
- PROPOSALS: A financial conflict of interest may exist. The proposal may be submitted, but if the grant is awarded, research may not begin until an approved management plan is in place and the sponsor has been notified.
- UPDATES: A financial conflict of interest may exist. No research may go forward until an approved management plan is in place and the sponsor has been notified.

Institutional Official

Date: _____

INSTITUTIONAL SUBRECIPIENT FCOI DISCLOSURE FORM 2

Many sponsors require that NRHI determine if a subrecipient institution representing an “investigator” has a compliant financial conflict of interest (FCOI) policy, and require the subrecipient to disclose information should a FCOI be present. These sponsors include the United States Public Health Service (PHS), which includes the National Institutes of Health (NIH) and other agencies. The term “investigator” means any person on behalf of the subrecipient who is responsible for the design, conduct, or reporting of research funded or proposed for such funding by that sponsor, including a consultant or collaborator, as applicable. The following information is requested to ensure compliance with the requirements.

Subrecipient Information	Sponsor & NRHI Information
Subrecipient’s Legal Name:	Sponsoring Agency:
Address:	Project Title:
Name of Each Investigator:	Sponsor’s Identification Number for the Project:
	Name of NRHI PI:

CONFLICT OF INTEREST (CHECK APPLICABLE BOX)

Subrecipient hereby certifies it has implemented and is enforcing a written policy of financial conflict of interest compliant with the Public Health Service (PHS) provisions of 42 CFR Part 50, Subpart F and 45 CFR Part 94. All individuals responsible for the design, conduct or reporting of research for the proposal have made the required disclosures to the subrecipient’s institutional official in accordance with the subrecipient's policy. Subrecipient shall report any financial conflict of interest to NRHI’s designated representative. Such report shall be made before expenditure of funds authorized by the sponsor and within 30 days of any subsequently identified financial conflict of interest.

Yes **No** Subrecipient is registered as an organization with a PHS-compliant FCOI policy with the FDP Clearinghouse: http://sites.nationalacademies.org/PGA/fdp/PGA_070596.



Subrecipient **HAS NOT** implemented a written policy of financial conflict of interest compliant with PHS provisions of 42 CFR Part 50, Subpart F and 45 CFR Part 94. NRHI’s Financial Conflict of Interest Disclosure Form has been completed and is attached for each individual who is responsible for the design, conduct or reporting of the research for the proposal (i.e. the “investigator”). The form will be completed and returned to the appropriate office indicated below at the following times:

- No later than at the time of application for funded research and before funds can be released;
- Within 30 days of discovering or acquiring a new Significant Financial Interest;
- At least annually during the period of the award.

Signature of Institution’s Authorized Official

Signature: _____ Date: _____

Name: _____ Title: _____

Return the completed form(s) to mwilson@nrhi.org. Please call 207-747-5104 with any questions.

FINANCIAL CONFLICT OF INTEREST DISCLOSURE FORM

To Be Completed and Signed By the Investigator

For you the investigator, your spouse/partner and dependent children, identify significant financial interests (SFI) that are reasonably related to the sponsored research, and meet any of the following criteria: (A) any remuneration received from an external entity at present or in the 12 months preceding the disclosure that totals or exceeds \$5,000 (the \$5,000 threshold applies to salary, royalties, and other payments aggregated for the individual, one's spouse/ partner and dependent children); (B) publicly-traded equity if the value of the equity (plus any remuneration) meets or exceeds \$5,000; (C) any level of ownership of privately-held equity regardless of the dollar value. **You do not need to disclose any financial interests from your employer, from a U.S. Federal, state or local government agency, from a U.S. institution of higher education, a U.S. academic teaching hospital, medical center, or a U.S. research institute affiliated with a U.S. Institution of higher education.** Refer to the full definition in the following page for additional information.

I do not have any SFI (proceed to and complete certification section below)

I disclose the following SFI (complete the table below and complete certification section below)

Name:	Mail Address:
Institution:	Telephone Number:
	Email Address:

			Approximate value of the financial interest		
Name of Earned Income Source(s)	Income Recipient (Investigator, Spouse/Partner, Dependent Child, or combination)	SFI Type (salary, royalty, equity, stocks, consulting fees, honoraria, etc.)	\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

For travel disclosures, please provide the following additional detail:

Sponsor	Destination	Start / End Date	Purpose

Prior to submitting this form, please review your entries for accuracy then sign and date the form.

Certification: By signing this form, as the investigator, I certify that the above entries are true and complete to the best of my knowledge and belief, and that I have reviewed the training slides. I understand and agree that it is my responsibility to update this information promptly if my significant financial interests related to this study's research activities change and at least annually during the period of the award. I understand and agree with the sponsored travel requirement as outlined in the documents. I will report qualified sponsored travel to NRHI within 30 days of the conclusion of the trip.

Name (Please Print)

Signature

Date (MM/DD/YYYY)

SIGNIFICANT FINANCIAL INTEREST (SFI)

Significant Financial Interest:

Anything of monetary value that meets any of the following criteria (when combined for you, your spouse or partner and/or your dependent children):

- Income >\$5,000 (U.S. dollars) over the past 12 months, including salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, royalties);
- As of the date of disclosure, any combination of income and equity in a publicly traded company >\$5,000 (U.S. dollars) (equity is any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value);
- Any equity interest in a non-publicly traded company, i.e. a privately owned company (equity is any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value);
- Income >\$5,000 (U.S. dollars) for intellectual property rights (e.g. royalties, licensing fees, etc.)

Significant Financial Interest does NOT include:

- Financial interests or activities that do not relate to your professional work at your employer organization;
- Salary support received through your organization or salary support through your organization's administered sponsored awards;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

SPONSORED TRAVEL FAQS

You are NOT required to disclose travel expenses if you are NOT responsible for the design, conduct or reporting of research funded by the Public Health Service (PHS) or other agencies/sponsors that have adopted the PHS regulations (including NIH).

You must disclose third party paid travel related to your institutional responsibilities If you ARE responsible for the design, conduct or reporting of research funded by the PHS (or other agencies/sponsors that have adopted the PHS regulations):

Third party paid travel means:

- Third party directly pays in whole or in part for travel on your behalf;
- You pay for travel and third party reimburses you in whole or in part;
- Your institution pays in whole or in part for travel and the third party reimburses your institution;
- PHS regulations require you to disclose travel paid by:

- Paid for by external professional organizations and societies, academic journals and publishing companies; and
- ANY travel reimbursed or sponsored by a foreign institution of higher education or the government of another country.

PHS regulations exclude travel paid by:

- Your institution or funded by a sponsored award to your institution;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

Additional examples are provided in the following chart:

Travel paid for by industry (directly paid to the individual, not through NRHI)	Yes
Travel paid for by a non-profit foundation	Yes
Travel paid for by a professional society (e.g. American Cancer Society, European Society for Pediatric Infectious Diseases)	Yes
Travel to a university paid for by the university to give a lecture	No
Travel to a board meeting in another state paid for by the American Heart Association	Yes
Travel to an advisory board meeting for a nonprofit for which you are reimbursed	Yes
Travel paid for by the American Cancer Society to an academic meeting to present NIH grant-funded research	Yes
Travel to another university to give a seminar where the university reimburses you, but the university received funding for the seminar from a pharmaceutical company	No, if the reimbursement came from university
Travel that combines a trip to an advisory board paid for by the company and a family vacation for which I am paying for myself	The vacation part of the trip must be paid for by personal funds and not by the company that is paying for the business trip. (only need to disclose the duration of the business portion of the trip)

INDEPENDENT CONTRACTOR SUBRECIPIENT FCOI DISCLOSURE FORM 3

Many sponsors require that NRHI determine if a subrecipient institution representing an “investigator” has a compliant financial conflict of interest (FCOI) policy, and requires the subrecipient to disclose information should a FCOI be present. These sponsors include the United States Public Health Service (PHS), which includes the National Institutes of Health (NIH) and other agencies. The term “investigator” means any person on behalf of the subrecipient who is responsible for the design, conduct, or reporting of research funded or proposed for funding by that sponsor, including a consultant or collaborator, as applicable. The following information is requested to ensure compliance with the requirements.

Subrecipient Information	Sponsor & NRHI Information
Subrecipient’s Legal Name:	Sponsoring Agency:
Address:	Project Title:
Name of Investigator (if different than above):	Sponsor’s Identification Number for the Project:
	Name of NRHI PI:

CONFLICT OF INTEREST (CHECK APPLICABLE BOX)

Subrecipient hereby certifies it has implemented and is enforcing a written policy of financial conflict of interest compliant with the Public Health Service (PHS) provisions of 42 CFR Part 50, Subpart F and 45 CFR Part 94. The investigator responsible for the design, conduct or reporting of research for the proposal has made the required disclosures in accordance with the subrecipient's policy. Subrecipient shall report any financial conflict of interest to NRHI’s designated representative. Such report shall be made before expenditure of funds authorized by the sponsor and within 30 days of any subsequently identified financial conflict of interest.

Yes **No** Subrecipient is registered as an organization with a PHS-compliant FCOI policy with the FDP Clearinghouse: http://sites.nationalacademies.org/PGA/fdp/PGA_070596.

Subrecipient **HAS NOT** implemented a written policy of financial conflict of interest compliant with PHS provisions of 42 CFR Part 50, Subpart F and 45 CFR Part 94. Subrecipient will complete the attached NRHI Financial Conflict of Interest Disclosure Form and return them to the appropriate office indicated below at the following times:

- No later than at the time of application for funded research and before funds can be released;
- Within 30 days of discovering or acquiring a new Significant Financial Interest;
- At least annually during the period of the award.

DEBARMENT AND SUSPENSION

Is the investigator proposed to participate in this project debarred, suspended or otherwise excluded from or ineligible for participation in federal dept., agency, assistance programs or activities?

Yes (If “Yes”, explain in below) No

Signature of Independent Contractor

Signature of Subrecipient: _____ Date: _____

Name: _____ Title: _____

Return the completed form(s) to mwilson@nrhi.org. Please call 207-747-5104 with any questions.

**INDEPENDENT CONTRACTOR SUBRECIPIENT FCOI DISCLOSURE FORM
To Be Completed and Signed By the Investigator**

SIGNIFICANT FINANCIAL INTERESTS

For you the investigator, your spouse/partner and dependent children, identify significant financial interests (SFI) that are reasonably related to the sponsored research, and meet any of the following criteria: (A) any remuneration received from an external entity at present or in the 12 months preceding the disclosure that totals or exceeds \$5,000 (the \$5,000 threshold applies to salary, royalties, and other payments aggregated for the individual, one's spouse/ partner and dependent children); (B) publicly-traded equity if the value of the equity (plus any remuneration) meets or exceeds \$5,000; (C) any level of ownership of privately-held equity regardless of the dollar value. **You do not need to disclose any financial interests from your employer, from a U.S. Federal, state or local government agency, from a U.S. institution of higher education, a U.S. academic teaching hospital, medical center, or a U.S. research institute affiliated with a U.S. Institution of higher education.** Refer to the full definition in the following page for additional information

- I do not have any SFI (proceed to and complete certification section below)
- I disclose the following SFI (complete the table below and complete certification section below)

Name:	Mail Address:
Institution:	Telephone Number:
	Email Address:

Identify the source of the SFI	Identify the Recipient (Investigator, Spouse/Partner, Dependent Child, or combination)	Identify the SFI Type (e.g., salary, royalty, equity, stocks, consulting fees, honoraria, etc.)	Approximate value of the financial interest		
			\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

SPONSORED/REIMBURSED TRAVEL

Provide the Following Fields Below (refer to the FAQs on the following page for additional information)

Sponsor	Destination	Start / End Date	Purpose

Prior to submitting this form, please review your entries for accuracy then sign and date the form.

Certification: By signing this form, as the investigator, I certify that the above entries are true and complete to the best of my knowledge and belief, and that I have reviewed NRHI's policy and the training slides. I understand and agree that it is my responsibility to update this information promptly if my personal or financial interests related to this study's research activities change and at least annually during the period of the award. I understand and agree with the sponsored travel requirement as outlined in the documents. I will report qualified sponsored travel to NRHI within 30 days of the conclusion of the trip.

Name (Please Print)

Signature

Date (MM/DD/YYYY)

SIGNIFICANT FINANCIAL INTEREST (SFI)

Significant Financial Interest:

Anything of monetary value that meets any of the following criteria (when combined for you, your spouse or partner and/or your dependent children):

- Income >\$5,000 (U.S. dollars) over the past 12 months, including salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, royalties);
- As of the date of disclosure, any combination of income and equity in a publicly traded company >\$5,000 (U.S. dollars) (equity is any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value);
- Any equity interest in a non-publicly traded company, i.e. a privately owned company (equity is any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value);
- Income >\$5,000 (U.S. dollars) for intellectual property rights (e.g. royalties, licensing fees, etc.)

Significant Financial Interest does NOT include:

- Financial interests or activities that do not relate to your professional work at your employer organization;
- Salary support received through your organization or salary support through your organization's administered sponsored awards;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

SPONSORED TRAVEL FAQS

You are NOT required to disclose travel expenses if you are NOT responsible for the design, conduct or reporting of research funded by the Public Health Service (PHS) or other agencies/sponsors that have adopted the PHS regulations (including NIH).

You must disclose third party paid travel related to your institutional responsibilities If you ARE responsible for the design, conduct or reporting of research funded by the PHS (or other agencies/sponsors that have adopted the PHS regulations):

Third party paid travel means:

- Third party directly pays in whole or in part for travel on your behalf;
- You pay for travel and third party reimburses you in whole or in part;
- Your institution pays in whole or in part for travel and the third party reimburses your institution;
- PHS regulations require you to disclose travel paid by:

- Paid for by external professional organizations and societies, academic journals and publishing companies; and
- ANY travel reimbursed or sponsored by a foreign institution of higher education or the government of another country.

PHS regulations exclude travel paid by:

- Your institution or funded by a sponsored award to your institution;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

Additional examples are provided in the following chart:

Travel paid for by industry (directly paid to the individual, not through your own institution)	Yes
Travel paid for by a non-profit foundation	Yes
Travel paid for by a professional society (e.g. American Cancer Society, European Society for Pediatric Infectious Diseases)	Yes
Travel to a university paid for by the university to give a lecture	No
Travel to a board meeting in another state paid for by the American Heart Association	Yes
Travel to an advisory board meeting for a nonprofit for which you are reimbursed	Yes
Travel paid for by the American Cancer Society to an academic meeting to present NIH grant-funded research	Yes
Travel to another university to give a seminar where the university reimburses you, but the university received funding for the seminar from a pharmaceutical company	No, if the reimbursement came from university
Travel that combines a trip to an advisory board paid for by the company and a family vacation for which I am paying for myself	The vacation part of the trip must be paid for by personal funds and not by the company that is paying for the business trip. (only need to disclose the duration of the business portion of the trip)