



Financial Conflict of Interest (FCOI)

I. Introduction

Mirimus Inc. is dedicated to creating a research climate that promotes objectivity in research. As such, the purpose of this Financial Conflict of Interest Policy is to ensure the objectivity with which research projects are designed by identifying and managing any potential conflicts of interest between Mirimus personnel's research responsibilities and their personal financial interests.

This policy is designed to ensure that Mirimus Inc. (hereafter, "Mirimus") is in full compliance with federal regulations when applying for or receiving NIH funding, as put forth in the National Institutes of Health guidelines (see <https://grants.nih.gov/grants/policy/coi/index.htm>).

This policy applies to all Investigators (as defined by the policy) who are involved with NIH-funded research by means of a grant or cooperative agreement.

II. Definitions

- a. **Disclosure:** The investigators disclosure of SFI to their institution.
- b. **Financial conflict of interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
- c. **Financial interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- d. **Investigator:** 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 NIH, or proposed for such funding, which may include, for example, collaborators, consultants, or contractors.
- e. **Institutional Official:** The individual within Mirimus who has been designated to solicit and review disclosures from Investigators of significant financial interests related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official will be the Head of Human Resources.
- f. **Institutional Responsibilities:** An Investigator's professional activities on behalf of Mirimus.
- g. **PHS:** The Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health (NIH).
- h. **Research:** 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. 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).
- i. **Significant Financial Interest (SFI):**
 - i. A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonable appears to be related to the Investigators 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 disclosure, when aggregated exceeds \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interests (e.g. stock, stock options, or other ownership interest) or
 3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- ii. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education.
 - iii. Significant financial interest does NOT include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirements 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 a federal, state or local government agency an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state or local government agency an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

III. Training

- a. Mirimus shall 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 relevant regulations, 45 CFR subtitle A, subchapter A, part 94, and
- b. Mirimus requires each Investigator to complete training regarding the same prior to engaging in research related to any NIH-funded contract and at least every four years, and immediately when any of the following circumstances apply:
 - i. Mirimus revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators
 - ii. An Investigator is new to Mirimus or
 - iii. Mirimus finds that an Investigator is not in compliance with the Mirimus' financial conflict of interest policy or management plan.
- c. Investigators should contact the Head of Human Resources to schedule trainings.

IV. Disclosure

- a. Investigator Disclosure Requirements:

- i. Mirimus requires 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 date of submission of the Institution's proposal for PHS-funded research.
 - ii. Mirimus requires 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 5.5.1 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).
 - iii. Mirimus requires each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
 - b. Institutional Official Responsibilities:
 - i. 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.
 - ii. Review and certify Significant Financial Interest Disclosure Form and determine if a conflict of interest exists with the NIH proposal.
 - iii. Certify that all investigators on the proposal have submitted a disclosure form.
 - c. Review of Financial Disclosures
 - i. If a Significant Financial Interest Disclosure Form reveals a Significant Financial Interest, as defined above, Mirimus' Institutional Official shall promptly review the form, together with supporting documentation, to make a determination of whether it constitutes a FCOI. A FCOI exists when the Institutional Official reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Mirimus may involve the Investigator in the Institutional Official's determination of whether a significant financial interest is related to the NIH-funded research.
 - d. Managements of FCOI
 - i. If the Institutional Official determines that a FCOI exists, they must require the creation of and approve a written plan for the management of the FCOI before related research may proceed. The Investigator, in cooperation with Mirimus, shall develop and present to the Institutional Official a Conflict-of-Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by the Significant Financial Interest.
 - ii. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:
 1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 4. Modification of the research plan;
 5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 6. Reduction or elimination of the financial interest (e.g., sale of an equity interest);

7. Severance of relationships that create financial conflicts.
- iii. No expenditures on PHS awards will be permitted until the Investigator has complied with the disclosure and training requirements of this policy and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of the FCOI.
- iv. Mirimus shall monitor Investigator compliance with the FCOI management plan on an ongoing basis until the completion of the PHS-funded research project.
- v. If Mirimus identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, Mirimus is not required to submit a FCOI report to the respective agency.

V. Reporting FCOI

- a. Sponsoring agency.
 - i. If the Institutional Official determines that any Significant Financial Interests is an FCOI, the Institutional Official shall provide to the PHS sponsoring agency an FCOI report regarding the FCOI and ensure that Mirimus has implemented a management plan in accordance with this policy. The FCOI report must be provided to the PHS sponsoring agency in accordance with its specific requirements within 60 days of the original disclosure and before any funds are expended under a PHS-funded research project, and it must include sufficient information to enable the PHS awarding agency to understand the nature and extent of the financial conflict and assess the appropriateness of the Mirimus' management plan.
 - ii. If PHS funding for the project comes via a subaward agreement, the FCOI report shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS sponsoring agency.
- b. Public request.
 - i. As required by sponsoring agency regulations, information on Financial Conflicts of Interest will be made available to members of the public in response to inquiries to the Institutional Official within 5 business days of receipt of such requests

VI. Compliance

- a. If the failure of an Investigator to comply with Mirimus' FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Mirimus shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Mirimus for further action, which may include directions to Mirimus on how to maintain appropriate objectivity in the PHS-funded research project.
- b. The PHS Awarding Component and/or HHS may inquire at any time (before, during, or after award) into any Investigator disclosure of financial interests and Mirimus' review of, and response to, such disclosure, regardless of whether or not the disclosure resulted in the Mirimus' determination of a financial conflict of interest. Mirimus is required to submit, or permit on site review of, all records pertinent to compliance with this Policy. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that Mirimus has not managed the financial conflict of interest in accordance with this part. The PHS Awarding Component may determine that issuance of a Stop Work Order by the Contracting Officer or other enforcement action is necessary until the matter is resolved. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by Mirimus as required by this Policy, Mirimus shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

VII. Subrecipient

- a. If Mirimus carries out the PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), Mirimus (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by
 - i. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
 1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this Policy. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;
 2. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest 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 Policy;
 3. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest 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 Policy.
 - ii. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this Policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

VIII. Record Maintenances

Mirimus 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 sponsor or, where applicable, from other dates specified in 45 C.F.R. 75.361. Access to such records will be limited to the faculty member, authorized institutional officials and others who have legal right to review the records.

IX. Public Accessibility

- a. Mirimus shall maintain, update, and enforce this Policy, and make it available via a publicly accessible website.
- b. Prior to expending any funds under a PHS-funded grant or cooperative agreement, Mirimus shall ensure public accessibility to information concerning an FCOI held by a senior/key personnel member by providing a written response to any written request, such response to be postmarked or dated (if replying by electronic means) within five (5) business days of the receipt of the written request. Such information shall consist of that required to be provided under the FCOI Regulations, shall be updated at least annually and within 60 days of the receipt or identification of information concerning an additional significant financial interest, and shall remain available for three years from the date the information was most recently updated.