

FINANCIAL CONFLICT OF INTEREST POLICY (Effective Dec 1, 2020)

1. Scope

1.1. This policy applies to anyone involved in research, management, or related services and responsible for the design, conduct, or reporting of research funded or proposed for funding by external sources. This policy is compliant with federal regulations 42 CFR Part 50 and 45 CFR Part 94 Department of Health and Human Service Final Rule with an effective date of September 26, 2011. The revised 2011 regulation does not apply to Phase I SBIR/STTR applications but the revised 2011 regulation does apply to Phase II SBIR/STTR applications/awards.

2. Policy

2.1. This policy aims to promote objectivity in research by establishing standards to prevent any Financial Conflict of Interest (FCOI) to influence the design, conduct, or reporting of research conducted by Clinacuity.

2.2. This policy fulfills federal regulations requiring institutions receiving federal funding to have in place a written, enforced policy and process to identify and manage, reduce, or eliminate conflicts of interest of persons engaged in the design, conduct, or reporting of federally funded Research.

2.2.1 This policy applies to each investigator (see definition) and their immediate family, which is defined as his/her spouse or domestic partner and dependents.

2.2.2. This policy applies to subrecipients related to PHS funded proposals and awards.

2.2.2.1 The responsibility to identify, manage, and report significant financial conflicts of interests only applies to subrecipients when funds flow down or projects are funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services, including the National Institutes of Health (NIH).

2.2.2.2 When the subrecipient will be following his/her own institutional FCOI policy, Clinacuity will obtain a written certification from the subrecipient organization that its FCOI policy complies with the applicable sponsoring agency regulations regarding the identification, management, and reporting of FCOIs. Additionally, the subrecipient agreement will require the subrecipient organization to report identified FCOIs for its investigators to Clinacuity and will specify an acceptable time frame for this reporting that will allow Clinacuity to in turn, report these FCOIs to the sponsoring agency as required.

2.2.2.3 If a subrecipient cannot certify that their FCOI policy and procedures meet sponsoring agency regulations, then the subrecipient organization will be required to adhere to Clinacuity policy and procedures, and to submit subrecipient investigator disclosures to Clinacuity. The timeframe for submitting disclosures must be consistent with federal requirements. In addition, the subrecipient investigator(s) must complete training prior to engaging in PHS funded research at least every four years during the award period.

2.3. Clinacuity is committed to completely disclosing, appropriately reviewing, and robustly managing identified conflicts.

2.4. Anyone responsible for the design, conduct, or reporting of research funded or proposed funding by external sources.

2.4.1. Individuals are responsible for complying with this policy and for disclosing any Significant Financial Interest (SFI) to Clinacuity.

2.5 Significant Financial Interest means:

- With regards to a publicly traded entity – a significant financial interest exists if the value of any remuneration (salary and any payment for services not otherwise identified as salary) received from the entity in the twelve months preceding the disclosure and the value of any equity interest (includes any stock, stock option, or other ownership interest) in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- With regards to any non-publicly traded entity – a significant financial interest exists if the value of any remuneration and any equity interest received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or their spouse or domestic partner and dependents) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

2.6. Disclosure Policies and Procedures:

2.6.1. The Privacy and Compliance Officer is responsible for management of Conflicts of Interest. See Section 2.8.

2.7. Investigator responsibilities

2.7.0 Anyone responsible for the design, conduct, or reporting of research funded or proposed for funding by external sources must disclose all significant financial interests (and those of his/her spouse, and dependent children) by completing a FCOI Screening and Disclosure Form.

2.7.1 Disclose all significant financial interests prior to the time a proposal for external funding is submitted. The initial disclosure process will coincide with the normal proposal routing/approval process.

2.7.2 Complete an annual disclosure form at the beginning of each fiscal year during the period of an award.

2.7.3 Update the disclosure within 30 days of discovery or acquisition (e.g. through purchase, marriage, or inheritance) of a new significant financial interest (including those of the individual's spouse and dependents), and at least annually throughout the life of a sponsored agreement.

2.7.4 Comply with FCOI management plans instituted by Clinacuity.

2.7.5 Complete FCOI training via the method/curriculum approved by Clinacuity.

- This is required prior to engaging in externally sponsored research funded by external sources.
- Completed at least every 4 years during the award period.
- Completed when an investigator is new to an institution and has externally funded research.
- Completed in the event an investigator (see definition) is not compliant with this policy or a management plan instituted by Clinacuity.

2.7.6. Disclose the occurrence of any reimbursed or sponsored travel related to the investigator's institutional responsibilities. This includes travel paid for on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available to the project sponsor and/or Clinacuity. This may include:

- The purpose of the trip
- The identity of the sponsor/organizer
- The destination
- The duration
- Salary, royalties, remuneration paid by Clinacuity.
- Income from seminars, lectures, or teaching engagements sponsored by:
 - A federal, state, or local government agency
 - An institution of higher education
 - An academic teaching hospital
 - A medical center affiliated with an institution of higher education
 - A research institute affiliated with an institution of higher education

- Income from service on advisory committees or review panels sponsored by:
 - A federal, state, or local government agency
 - An institution of higher education
 - An academic teaching hospital
 - A medical center affiliated with an institution of higher education
 - A research institute affiliated with an institution of higher education
- Travel reimbursed or sponsored by:
 - A federal, state, or local government agency
 - An institution of higher education
 - An academic teaching hospital
 - A medical center affiliated with an institution of higher education
 - A research institute affiliated with an institution of higher education
 - Intellectual property rights that the investigator has assigned to Clinacuity or instances where an agreement exists to share royalties to such property rights with Clinacuity.
 - Unlicensed property that does not generate income.
- Income from investment vehicles or retirement accounts unless the investigator directly controls the investment decisions for these vehicles Management and Reporting of Financial Conflicts of Interest.

2.8 The Privacy and Compliance Officer is responsible for determination, resolution, or management of FCOI. In consultation with Clinacuity executive leadership, this individual shall review disclosures with a significant financial interest identified; determine whether any significant financial interests relate to proposed research; and if so, develop and implement a management plan that shall specify that actions that have been, and shall be, taken to manage the FCOI.

2.8.1. Prior to the expenditure of any funds, the Privacy and Compliance Officer is responsible for developing a management plan for any identified conflicts of interest.

2.8.2. Management plans may include, but are not limited to the following:

- Public disclosure of FCOI (e.g. when presenting or publishing research);
- 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;
- Modification of the research plan; responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest;
- Severance of relationships that create financial conflicts

2.8.3 Management plans will include at a minimum the following:

- Role and principal duties of the conflicted investigator in the research project.
- Conditions of the management plan.
- Requirements to safeguard the objectivity in the research project.
- Confirmation of the investigator's agreement to the management plan.
- The monitoring method to ensure investigator compliance.
- Other information as needed.

2.8.4 In the event of a FCOI, Clinacuity will notify the funding source and provide details of the management plan.

2.8.5 The Privacy and Compliance Officer will notify the Institutional Review Board (IRB) Clinacuity relies upon if the IRB has oversight of the research project/study.

3. Reason for Policy

3.1 This policy exists to ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any Financial Conflict of Interest of related parties.

3.2 Per federal regulations, Clinacuity is responsible for maintaining a written and enforced FCOI policy; managing, reducing, or eliminating identified conflicts; and reporting identified conflicts to the awarding

component. The reports denote the existence of a FCOI and Clinacuity's assurance that a plan has been implemented to manage, reduce, or eliminate the conflict.

4. Definitions

4.1. **Financial conflict of interest (FCOI):** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or a sponsored program.

4.2. **Financial interest:** Anything of monetary value, whether or not the value is readily ascertainable.

4.3. **Institutional responsibilities:** Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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.

4.4. **Investigator:** Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed funding, which may include, for example collaborators or consultants.

4.5. **Management:** Action taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure that the design, conduct, and reporting of research will be free from bias.

4.6. **Research:** 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).

4.7. **Significant financial interest:** Interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears related to the Investigator's institutional responsibilities.

4.7.1. With regard to any publicly traded or non-public 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.

4.8. **Disclosure of significant financial interests:** Investigator's disclosure of significant financial interest to an Institution.

4.9 **FCOI report:** Institution's report of a financial conflict of interest to the external sponsor, including the awarding component within PHS or PHS funded research.

4.10 **Senior/key personnel:** the 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 PHS by the Institution under this subpart.

5. Enforcement

5.1. The Privacy and Compliance Officer is the designated institutional authority.

5.2. Violations of this Policy and implementing procedures, including the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest, will result in appropriate disciplinary action. Additionally, individuals may be subject to the loss of institutional resources and privileges.