CLINICAL TOOLS' FINANCIAL CONFLICT OF INTEREST POLICY

This is Clinical Tools' Financial Conflict of Interest Policy, presented in accordance with NIH requirements, as described in 4.1.10 Financial Conflict of Interest of the NIH Grants Policy Statement, revised April 2021 see https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm?Highlight=fcoi.

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POLICY STATEMENT

As a professional research corporation, Clinical Tools is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. Clinical Tools has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for NIH-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to Clinical Tools' other activities including continuing medical education.

Clinical Tools' goal is to eliminate and effectively manage when elimination is not possible actual or potential financial conflicts of interest.

KEY POINT

SBIR grant/contract Investigators or Consultants with Significant FCOI will be removed from the project with the permission of the NIH Project Officer. Faculty (staff or consultants) with Significant FCOI will likewise not be involved in the content of Continuing Medical Education.

REASON FOR POLICY

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought[see below] and 45 CFR Part 94, Responsible Prospective Contractors.

These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

DEFINITIONS

From Subpart F—Promoting Objectivity in Research
§50.603 Definitions.
https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

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

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

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 responsibilities means an 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.

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, or proposed for such funding, which may include, for example, collaborators or consultants.

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

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 under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

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. 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means 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.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) 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 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 includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-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, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Significant financial interest does **not** include the following:

- Salary, royalties, or other remuneration paid by Clinical Tools (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Clinical Tools, including that paid for intellectual property rights assigned or licensed to Clinical Tools and agreements to share in royalties related to such rights;
- Any ownership interest in Clinical Tools (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- 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 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; 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

PROCEDURES

Responsibilities of Clinical Tools' Designated Official

The Designated Official or his/her designee shall be responsible for the following:

- Informing Clinical Tools Investigators of their obligations under this policy and any related regulations;
- Reviewing disclosures of significant financial interest with Clinical Tools' Administrator to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;
- Screening and managing potential financial conflicts of interest;
- Maintaining all records relating to disclosures of financial interests, Clinical Tools' review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

For NIH and any other PHS-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide Clinical Tools with sufficient assurances to enable Clinical Tools' compliance with all applicable laws or regulations. To this end, the written agreement between Clinical Tools and the subrecipient will specify whether Clinical Tools' or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
    - Obtain certification from the subrecipient that its policy complies with Clinical Tools' policy and the applicable regulations (absent such certification, Clinical Tools' policy will apply to the subrecipient's Investigators, and
    - Establish time periods for subrecipient reporting of financial conflicts of interest to Clinical Tools that enable Clinical Tools to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If Clinical Tools' policy will apply to the subrecipient Investigators, Clinical Tools will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

Internal Reporting Requirements

For PHS-funded research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to Clinical Tools' Administrator.

This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research.

SFID Forms will be provided to Investigators in conjunction with the annual training and will be otherwise made available on the intranet.

Clinical Tools' Administrator will review SFID submissions with the Designated Official. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Clinical Tools staff who create content for Continuing Medical Education may also be required to complete the Financial Conflict of Interest form required to be in compliance with the standards of the *Accreditation Council for Continuing Medical Education*.

Investigators are expected to submit an updated SFID Form during the period of the award as necessary (at least annually for PHS-funded research). The annual update will typically be done in conjunction with completion of the annual training and Research Misconduct memo.

Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

Determination and Management of Financial Conflicts of Interest

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If Clinical Tools determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- SBIR grant/contract Investigators or Consultants with Significant FCOI will be removed from the project with the permission of the NIH Project Officer.

In addition

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
    - ANY FCOI will be disclosed when Continuing Medical Education is involved.
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Clinical Tools may require the management of conflicting financial interests in other ways as it deems appropriate.

External Reporting Requirements

Clinical Tools will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Clinical Tools will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations.

The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Clinical Tools has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Clinical Tools will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an

Investigator or not previously reviewed or managed by Clinical Tools (e.g., not reviewed or reported by a subrecipient in a timely manner), Clinical Tools will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Clinical Tools will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Clinical Tools will provide HHS with information relating to any Investigator disclosure of significant financial interests; Clinical Tools' review of, and response to, such disclosure; and whether the disclosure resulted in Clinical Tools' determination of a financial conflict of interest.

Confidentiality

Clinical Tools will, to the extent possible, protect the confidentiality of disclosures. In every instance, Clinical Tools will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Clinical Tools staff only on a need-to-know basis and will not be disclosed outside of Clinical Tools unless necessary to comply with contractual, legal, or regulatory requirements.

Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), Clinical Tools may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Clinical Tools shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- Clinical Tools will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that a clinical PHS-funded research project 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 neither disclosed nor managed, Clinical Tools shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Training and Education

Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site. https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Clinical Tools requires Investigators to complete such training annually, AND when any of the following occurs:

- Clinical Tools revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Clinical Tools; or
- Clinical Tools finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

Retention of Records

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information consistent with Clinical Tools' Record Retention policy. For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Clinical Tools with respect to each financial conflict of interest will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

POINT OF CONTACT

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