

Chicago Association for Research and Education in Science

FINANCIAL CONFLICT OF INTEREST – OBJECTIVITY IN RESEARCH

The purpose of this policy is to promote objectivity in research by establishing standards that create a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from conflicting financial interests of investigators.

A conflict of interest (actual or perceived) occurs when any financial or other arrangement, situation, or action affects or could be perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Conflicts may be related to financial gain, reputation, promotion, or to the role of research investigator vs. health care provider, among others.

A researcher is required to disclose a significant financial interest when he or she, any of his or her family, or any associated entity possesses a significant financial interest in a research activity, managed by the Chicago Association for Research and Education in Science (CARES), that is related to his or her research conducted at any CARES related VA facility.

CARES investigators are also subject to the conflict of interest policies of the federal government and institutions such as their local VA and University with whom they may have an affiliation or appointment, and have a responsibility to disclose financial interests in research according to the policies of those institutions.

This policy covers all CARES administered research projects or programs and closely adheres to the policy as promulgated in the 2011 revised Department of Health and Human Services (DHHS) Financial Conflict of Interest (FCOI) regulation. Research supported by U.S. Public Health Service (PHS) funding has additional requirements addressed in the section for Additional Requirements for PHS Awards and in definitions noted below.

DEFINITIONS

Institutional Responsibilities on behalf of CARES include research and service on the CARES Board of Directors.

Investigator means the principal investigator, co-investigators, and other individuals who are responsible for the design, conduct, or reporting of research. It is not intended to apply to individuals who provide primarily technical support or who are purely advisory and without direct access to the data (e.g., control over its collection or analysis), unless they are in a position to influence the study's design, reporting, or results or have privileged information as to the outcome. Senior or key personnel identified on a grant application or progress report, consultants and post-doctoral fellows may or may not be included as Investigators.

Research means a systematic investigation 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 and product development.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's spouse or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

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;

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

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

A significant financial interest 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, including intellectual property rights assigned to the Institution 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 by these vehicles;
- 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, 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 U.S. federal, state, or local government agency, U.S. Institutions of higher education, U.S. academic teaching hospitals, U.S. medical centers, or U.S. research institutes that are affiliated with institutions of higher education.

Financial Interests Received from Foreign Institutions

All financial interests must be disclosed if they are from foreign institutions. This requirement includes financial interests received from foreign institutions of higher education or the government of another country.

DISCLOSURE AND REVIEW

For all research projects, Investigators must disclose financial interests prior to review and approval by the Research & Development (R&D) Committee.

For CARES Board members, each Director must disclose annually for Board review or prior to any vote that may have a potential conflict of interest.

For Investigators under the PHS policy, disclosure is additionally required at the time of application and at least annually thereafter as delineated in the Financial Conflict of Interest Guidelines for PHS Awards. Disclosure should include the relationship of the financial interest to their institutional duties.

Investigators are responsible for disclosing new or changed financial relationships as they occur but no later than within 30 days. These will be reviewed in the same manner as original disclosures.

Retrospective reviews will be required for significant financial interests not disclosed in a timely manner.

CARES reviews potential conflicts of interest for research through the local VA Research & Development (R&D) Committee. This committee reviews proposed research and makes recommendations regarding management of conflicts of interest. Whenever there is a significant financial interest, disclosures must be submitted by Investigators to CARES. CARES will refer significant financial interests related to institutional duties to the local R&D for review.

For VA investigators, the R&D Committee relies on, among other rules, federal guidelines contained in 5 CFR Part 2635 and 18 USC§208.

The R&D Committee meets on a regular basis and considers Conflict of Interest issues on an as needed basis. Its membership is reviewed and authorized on a federal fiscal year basis. The R&D Committee and CARES management document decisions in the form of meeting minutes. These minutes include recommendations regarding management of the real or potential conflicts of interest disclosed by Investigators. Persons appointed to the R&D Committee are required to disclose their own potential conflicts of interest to the committee and recuse themselves from reviewing and voting on any matter in which they may have an interest.

In addition to CARES and PHS policy, as noted above, specific conflict of interest rules and ethics standards apply to VA investigators and are considered in the review.

CONFLICT OF INTEREST MANAGEMENT

The R&D Committee will consider all information obtained from the Investigator, CARES, VA, and the affiliated University in deciding how best to address conflicts of interest. Options for managing conflict of interest include, but are not limited to:

- Disclosure of significant financial interests to the public, human subjects, researchers and other participants, publishers, and/or conference organizers;
- Requiring additional disclosures or actions with respect to IRB or IACUC applications or materials;
- Monitoring of research by disinterested co-researchers or independent reviewers or committees capable of taking measures to protect research from bias;
- Disqualification from participation in activity affecting or affected by a technology transfer transaction;
- Requiring that investigator participation in the recruitment or consent of subjects be prohibited or restricted;

- Requiring that the significant financial interest be divested, restructured, or placed in a blind trust;
- Modification or severance of relationships that create potential conflicts of interest;
- Changing terms of the grant agreement or CRADA relating to the research;
- Requiring non-participation in any business transactions between the parties to agreements involving the research in question.

Conditions imposed by the R&D Committee must be met by the Investigator in order to receive approval to conduct a proposed research project. CARES will not expend funds in support of a research project until any significant financial interest has been reviewed by the R&D Committee and any conflict of interest has been satisfactorily managed or eliminated.

CARES will comply with sponsor requirements for ongoing reporting of FCOIs including management plans, retrospective reviews and mitigation reports. Any violation of this policy may require reporting to a sponsoring entity and affiliated institutions as appropriate.

RECORD RETENTION

All records relating to the disclosure of conflicts of interest and any action taken with respect thereto will be maintained for at least three years or as required by applicable government regulations, whichever is longer.

ADDITIONAL REQUIREMENTS FOR PHS AWARDS

Additional requirements for PHS awards are promulgated by the 2011 revised DHHS Financial Conflict of Interest (FCOI) regulation, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). Compliance with these regulations is delineated under the Financial Conflict of Interest Guidelines for PHS Awards found on the CARES website.

Investigators entering into consortium arrangements should be aware that CARES will include a requirement that subrecipient institutions comply with the PHS policy on Financial Conflict of Interest.

The PHS policy requires travel disclosure and training as defined below.

Travel and training requirements do not extend to Investigators' immediate family members (spouses and dependent children).

Disclosure Under PHS Awards

Investigators must disclose all significant financial interests as defined above and in addition include 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. However, 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; an academic teaching hospital; a medical center; or a research institute that is affiliated with an Institution of higher education.

Disclosures are required: (1) at the time of application for PHS-funding; (2) at least annually during the period of award; (3) within 30 days of acquiring or learning of a newly acquired significant financial interest; (4) within 30 days of an Investigator newly participating in the project; and (5) within 30 days of travel.

Mandatory Training

All Investigators involved in the design, conduct, or reporting of research will complete training at least once every four years.

Public Availability

In accordance with PHS policy, CARES makes identified FCOIs held by Investigators available to requestors within five calendar days of the receipt date of a written request.

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