

Research

Addendum C

Page 1 of 4

SCOPE

This Addendum applies to all individuals employed by or contracting or affiliated with CHI or a CHI Entity who are responsible for or are in the position to influence the design, conduct, or reporting of human subjects research at CHI or a CHI Entity facility, regardless of research funding source. Such individuals must comply with the provisions of this Research Conflicts of Interest Addendum which is compliant with 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

Individuals include:

- Full- or part-time CHI National or CHI Entity employees;
- Physicians and other healthcare providers, research assistants and nurses engaged in research activities;
- Trainees and students, who are involved in research-related activities, including, but not limited to, nursing, pharmacy, technicians, *et al.*; and
- Independent research contractors and consultants.

Federal regulations require entities engaged in human subjects research to have policies and procedures in place that ensure that investigators disclose any financial interests that may present perceived, potential or actual financial conflicts of interest. CHI aims to foster an environment in which objectivity in the design, conduct, and reporting of research is protected and the public trust in CHI and its mission is not compromised.

DEFINITIONS

In addition to the definitions in CHI Governance Policy No. 1, *Conflicts of Interest* (“COI Policy”), the following definitions apply to research conflicts of interest:

Financial Conflict of Interest means a financial interest that could directly or significantly affect the design, conduct or reporting of research.

Investigator means the principal investigator, co-investigators, project director and any other person, regardless of title, who is responsible for the design, conduct, evaluation, monitoring, expenditure of funds, or reporting of research, which may also include, for example, collaborators and consultants.

Key Research Personnel means the project director or principal investigator and any other individual identified by the institution in a grant application, progress report or other report submitted by CHI or a CHI Entity to any component of the Public Health Service (PHS) by CHI or the CHI

Research

Addendum C

Page 2 of 4

Entity, or those individuals listed on an IRB submission for a research project; submission to a biohazards committee; or submission to an Institutional Animal Care and Use Committee (IACUC). Additional information and requirements related to animal research is contained in both the CRP Research Addendum and the CRP Teaching Hospital and Academic Medical Center Addendum.

Research for the purposes of this Addendum includes all activities that involve living human beings, conducted in a systematic manner, and designed to develop or contribute to generalizable knowledge relating broadly to public health, including biomedical, behavioral and social sciences research.

Significant Financial Interest means a financial interest involving any of the following:

- Any remuneration received from any publicly traded entity plus any equity interest (e.g., stock, stock option or other ownership interest), as determined on the date of disclosure if the value, in the aggregate exceeds \$5,000;
- Any remuneration received from any non-publicly traded entity if the value, when aggregated, exceeds \$5,000;
- Any equity interest (e.g., stock, stock option, partnership interest, membership interest or other ownership interest) in a non-publicly traded entity on the date of disclosure regardless of value;
- Intellectual property rights and interests (e.g., patents and copyrights), royalties from such rights, or filing of the patent interest or effective date to share in rights to royalties; and
- All reimbursed or sponsored travel (travel paid on an investigator's behalf but not reimbursed by a CHI Entity) related to research responsibilities.

The following are excluded from the requirement to disclose:

- Remuneration from the CHI or a CHI Entity, if the investigator is employed by CHI or the CHI Entity;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or institutions 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 any service on advisory or review panels for such agencies or institutions;
- Income from investment vehicles, such as mutual funds and retirement accounts, provided that the investigator does not directly control the investment decisions made about these vehicles; and
- Travel that is reimbursed or sponsored by a federal, state, or local government agency, or institutions of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching

Research

Addendum C

Page 3 of 4

hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

ADDITIONAL CONSIDERATIONS

PHS-Funded Research

Additional requirements for the institution and investigators who participate in PHS-funded research include additional procedures when a financial conflict of interest is not identified or managed in a timely manner and procedures specified in 45 CFR Part 50. Additionally, investigators and institutions involved in PHS-funded research must comply with 42 CFR Part 50 Subpart F.

Requirement for Researcher Training in Financial Conflicts of Interest

As of August 2012, all investigators are required to receive training in financial conflicts of interest in research at least every four (4) years. CHI policy requires that all researchers receive this training. This includes research coordinators, research nurses, research assistants, etc. Refer to the COI Policy for the definition of researcher. There are multiple resources available for this training.

Maintaining Documentation and Providing Information to Requestors

Conflicts of Interest disclosures, other documentation used in the review of such disclosures, and relevant records shall be maintained in the COI software for a minimum of three (3) years following the completion of the research project that generated the disclosure statements, or until any relevant government, criminal, or civil proceeding has concluded. For PHS-funded research, such records shall be maintained as specified in 45 CFR 74.53(b) and 92.42(b).

CHI or the CHI Entity, as appropriate, will provide to any requestor (within five business days) a written response containing information on financial conflicts of interest the CHI Entity determines are related to the research as required by 45 CFR Part 94.

Applicable Regulations

Investigators must comply with all applicable state and federal laws and regulations, including those specifically related to financial conflicts of interest and objectivity in research. These provisions include, but are not limited to, Public Health Service Regulations (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94) and guidance material located in the National Institutes of Health (NIH) Grants Policy Statement (12/03).

Penalties for Violation of the Conflicts of Interest Policy and the Provisions of the Relevant Addenda

A Person who fails to disclose a perceived, potential or actual conflict of interest, or all material facts surrounding an actual or potential conflict, or fails to abide by the final decision regarding the conflict as required by this Policy and relevant addenda, may be subject to disciplinary or corrective actions such as employment termination, removal from a board or committee, possible loss or restriction of clinical privileges, or restriction of research activities in accordance with applicable laws, regulations, rules, contracts, and bylaws, etc.