Edward – Elmhurst Healthcare System Policy

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Manual:	System
Section:	Institutional Review Board
Policy #:	RSCH_019
Reviewer:	System Director, Institutional Review Board
	Reviewer Signature

Policies and procedures are guidelines and are not a substitute for the exercise of individual judgment. If you are reading a printed copy of this policy, make sure it is the most current by checking the on line version.

POLICY: INVESTIGATOR CONFLICTS OF INTEREST IN CLINICAL RESEARCH

Applicability:

Edward-Elmhurst Healthcare ("System")

Purpose / Policy Statement:

It is the policy of the System to promote scientific integrity, patient safety and investigator objectivity in human subjects research. Conflicts of interest on the part of investigators and other individuals responsible for the design, conduct or reporting of clinical research, if not identified, assessed and either eliminated or appropriately managed, can compromise the safety and well-being of human subjects and the integrity of study data and results.

This policy requires that individuals involved in the design, conduct or reporting of clinical research at System facilities disclose Significant Financial Interests through Corporate Compliance that could have an effect on how an individual conducts his/her professional responsibilities on behalf of the System, including research, research consultation, professional practice, and committee or board memberships. A conflict of interest exists when the System determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of research. The System will take action to eliminate or manage identified financial conflicts of interest in research through the mechanisms set forth in this policy.

This policy is intended to supplement and not circumvent other policies adopted by the System.

Definitions:

Clinical Research: a systematic investigation involving the participation of human subjects designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral health and social-sciences research, and including investigations funded and supported by the PHS or investigations regulated by the FDA. 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).
Clinical Study: Clinical Research being conducted or intending to be conducted at a Research Site.
Conflict of Interest: any activity, commitment or interest of an Investigator, including a Financial Conflict of Interest, that could directly and significantly affect the design, conduct or reporting of Clinical Research.
Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.
Financial Conflict of Interest (FCOI): a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Clinical Research.
Investigator: the project director, Principal Investigator or sub-investigator, Senior/Key Personnel, Clinical Study coordinators, and any other person, regardless of title or position, who is responsible for the design,

conduct or reporting of Clinical Research, which may include, for example, collaborators or consultants. "Investigator" also includes Subrecipient Investigators, who are those individuals or companies that the System may contract with to carry out a Clinical Study.

IRB: the System Institutional Review Board.

Research Integrity Officer ("RIO"): the person designated by the System to be responsible for disclosure and management of Conflicts in interest in research.

Research Site: the facility or site engaged in Clinical Research that is (i) under the jurisdiction of the System IRB; or (ii) contractually or otherwise affiliated with the System for the purpose of engaging in Clinical Research, including subcontractors or Subrecipients.

Significant Financial Interest: that is required to be disclosed means one or more of the following financial interests of an Investigator ***(and those of the Investigator's Immediate Family)*** that is with an individual or entity sponsoring, conducting or seeking to engage in a Clinical Study at a System Research Site and that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded or non-publicly traded entity, a disclosable Significant Financial Interest exists when the Investigator (or the Investigator's Immediate Family) holds any equity interest in the entity (e.g., stock, stock option, or other ownership interest). 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.
- A disclosable Significant Financial Interest exists if the value of any Compensation Arrangement received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000. For purposes of this definition, Compensation Arrangement includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Additionally, a disclosable Significant Financial Interest consists of any Compensation Arrangement received by the Investigator or the Investigator's Immediate Family, or to which the Investigator or the Investigator's Immediate Family is entitled, in which the value of the compensation could be affected by the Clinical Study outcome (for example, compensation would be higher for a favorable outcome than for an unfavorable outcome or tied to the sales of the drug, device or product).
- Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities(sponsored travel is travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available); provided, however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institution's RIO or RCOI Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest
- A disclosable Significant Financial Interest consists of intellectual property or other proprietary rights and interests (e.g. patents, copyrights, royalties, or licensing agreement) in the item being studied or tested that exceed $5,000 in value, upon receipt of income related to such rights or interest.

A Significant Financial Interest does not include the following interests, which are not required to be disclosed:

- 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;
- 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 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 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 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.

System: Edward-Elmhurst Health

Procedure:

A. Conflict of Interest (COI) and Policy Training:

a. The Office of the Edward-Elmhurst Health (EEH) IRB, on behalf of EEH Corporate Compliance, shall require that each Investigator is informed of this policy and its training requirements. If this policy is revised in a manner that affects the requirements of Investigators, the EEH IRB will inform all research sites.
b. All Investigators are required to complete the online research Conflict of Interest (COI) training module through the CITI (Collaborative Institutional Training Initiative) program (see **Exhibit A Instructions on How to Register with CITI)**. The CITI program offers both initial and refresher courses for all required training, including the Conflict of Interest Course. All Investigators are required to complete the Conflict of Interest training course immediately if:
   i. This policy is revised in any manner that affects the requirements of the Investigator, at the discretion of the Research Integrity Officer (RIO;
   ii. An Investigator is new to the System; or
   iii. The (RIO) or their designee, or the Research Conflicts of Interest Committee determines that an Investigator is not in compliance with this COI policy or any management plan approved by the Research Conflict of Interest Committee to manage an identified Conflict of Interest.
c. EEH CITI refresher courses are required every 3 years. The Office of the IRB or their designee shall maintain a record of training certifications of all Investigators completing CITI COI training.

B. Conflict of Interest Disclosure Requirements:
a. Each Investigator is required to disclose Significant Financial Interests involving themselves and their Immediate Family that are related to his or her Institutional Responsibilities. COI requirements and instructions for funded studies can be found in **Appendix D** of System policy **CMPR_G002 CONFLICT OF INTEREST.**

CROSS REFERENCE(S)

CMPR_G002_Conflict of Interest

Policy Committee Review:	Effective Date:	Current Policy Replaces Policy:
12/03/2014	01/01/2014	Edward Hospital Policy RSCH 019 Investigator Conflicts of Interest on Clinical Research
01/06/2015	01/07/2015	
Administrative changes	02/16/2015	
Administrative changes	12/03/2015	
01/05/2016	01/05/2016	

EXHIBIT A

Instructions on How to Register with CITI

If you have not completed CITI training before:

- Go to www.citiprogram.org and click on “Create an Account/Register" button located on the right-hand side of the page.
- Under “Select Your Organization Affiliation” type *Edward-Elmhurst Healthcare”*. Click “Continue to Step 2”
- In Step 7:
  - Question 10, select “yes” for the question: “Would you like to take the Conflicts of Interest Course”?
  - For Questions 1-9, please select any ancillary training that your research type will require (i.e. External IRB review, etc.)
- After finalizing your registration, click on the name(s) of the course(s) you need to complete. This will take you to the list of modules to complete.

- Once all modules are completed, print a completion certificate by using the “Print Report” link.

If you have completed CITI training before with another institution:

- Go to www.citiprogram.org and login to your profile.
- Click, “Click her to affiliate with another institution” at the bottom of the page.
- Type *Edward-Elmhurst Healthcare”*
- Follow the steps outlined above

If you have completed CITI training before at Edward-Elmhurst Healthcare and must renew your training:

- Go to www.citiprogram.org and login to your profile.
- Click on the name(s) of the course(s) you need to complete. This will take you to the list of modules to complete.
- Once all modules are completed, print a completion certificate by using the “Print Report”

Please contact the IRB office for questions about the CITI program requirements.