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Owner:	
Area:	*Office of Research Administration (IRB/ORA) Policy/Procedure*
References:	
Applicability:	*Edward Elmhurst Health System (All Locations)*

Investigator Conflicts of Interest in Clinical Trials, ORA_019

Policies and procedures are guidelines and are not a substitute for the exercise of individual judgment.

Purpose / Policy Statement:

It is the policy of Edward-Elmhurst Health ("EEH" or "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 trials, 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 is intended to supplement and not circumvent other policies adopted by the System.

EEH employees involved in the design, conduct or reporting of clinical trials must disclose Significant Financial Interests that could have an effect on how an individual conducts his/her professional responsibilities on behalf of the System to EEH Corporate Compliance. EEH Corporate Compliance will take action to identify and, if identified, eliminate or manage identified financial conflicts of interest in research through the mechanisms set forth in CMPR_G002.

The EEH Office of Research Administration (ORA), on behalf of EEH Corporate Compliance, will ensure 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 and/or their staff, the EEH ORA will inform all affected individuals.

Definitions:

Clinical Trial: a study, regardless of funding, where human participants are prospectively assigned specific interventions according to a research plan or protocol so that researchers can evaluate the effects of the intervention on biomedical or health-related outcomes. The interventions may use medical products (drugs, devices, and/or biologics), procedures, or changes to participants' behavior such as diets. Clinical trials may compare a new medical approach to a standard one, to a placebo, or to no intervention. Some clinical trials compare two or more interventions that are already approved, available, and/or in clinical practice.

Conflict of Interest (COI): A set of circumstances where an independent observer might reasonably determine that private interests (e.g. a personal financial relationship) unduly influence professional judgment or actions (consciously or unconsciously) regarding an individual or institution's professional obligations (e.g. patient care or decision making on behalf of EEH). This includes any activity, commitment or interest of an Investigator, including a Financial Interest, that could directly and significantly affect the design, conduct or reporting of research.

Financial Interest: An ownership or investment interest in a Business and and/or a compensation relationship with a Business.

- "Ownership or Investment" interest includes but is not limited to:
  - Stock, stock options, debt interests and any other ownership, potential ownership or investment rights in privately held entities;
  - Stock, stock options, debt interests and any other ownership, potential ownership or investment rights with an ownership of greater than 5% in publicly traded entities but excludes diversified mutual funds, pension funds or other institutional investment funds where the individual does no exercise direct control over the investments;
- "Compensation Relationship" includes, but is not limited to, the receipt or expectation to receive any remuneration such as consulting fees, honoraria, salary, rent or royalties.

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 trials, which may include, for example, collaborators or consultants. "Investigator" also includes sub-recipient Investigators, who are those individuals or companies that the System may contract with to carry out a clinical trial.

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

Procedure:

A. **Conflict of Interest Disclosure Requirements:**

1. Each Investigator is required to disclose Financial Interests involving themselves and their Immediate Family that are related to his or her Institutional Responsibilities. Please refer to System policy **CMPR_G002 CONFLICT OF INTEREST** for more information**.**

B. **Notification to Corporate Compliance of Study Activation and/or Changes in Research Staff:**

1. Investigators (or their designee) must inform EEH Corporate Compliance of the following:
   a. New Clinical Trial Submission – ***use COI Fax Form for A New Study****, available in the electronic IRB Document library.*
   b. Changes in Study Personnel – *use **COI Fax Notification for Changes to Existing Studies**, available in the electronic IRB Document library.*

C. **Conflict of Interest (COI) and Policy Training:**

1. All Investigators conducting clinical trials, regardless of funding, are required to complete the online research COI training module through the Collaborative Institutional Training Initiative (CITI) program (see " Instructions on How to Register with CITI", available on the EEH intranet under "Office of Research Administration"). The CITI program offers both initial and refresher courses for all required training, including the Conflict of Interest Course. EEH CITI refresher courses are required every 3

years.

2. All Investigators are required to complete the Conflict of Interest training course immediately if:
    a. This policy is revised in any manner that affects the requirements of the Investigator, at the discretion of the Research Integrity Officer (RIO);
    b. 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.

EXHIBITS:

CROSS REFERENCE(S)

CMPR_G002 Conflict of Interest

Current Policy Replaces:

RSCH_019 Investigator Conflicts of Interest

All revision dates: Nov 03, 2021, Nov 06, 2018

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date

Applicability

Ambulatory, Edward Elmhurst Health System, Edward Hospital, Elmhurst Hospital, Linden Oaks Behavioral Health, Plainfield Lab