

Edward – Elmhurst Healthcare System Policy

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Manual:
Section:
Policy #:

System
Compliance
CMPR_G002

Reviewer:

System Director, Internal Audit & Compliance

Reviewer Signature

POLICY: Conflict of Interest

Applicability:

EDWARD-ELMHURST HEALTHCARE (“System”)

The System expects that all joint ventures in which the System participates will have a conflict of interest policy that has been adopted by the joint venture’s governing board.

Purpose / Policy Statement:

PURPOSE

The purpose of the Conflict of Interest Policy is to protect the interests of Edward-Elmhurst Healthcare (“EEH”) when it is contemplating entering into a transaction or arrangement that might benefit the private interest of a Trustee or officer, or certain employees or agents of EEH.

POLICY STATEMENT(S)

This policy establishes standards for activities that may present a Conflict of Interest and for identifying, reporting and oversight of individual Conflicts of Interest. This policy applies to all members of the Board of Trustees and board committees, and officers, and certain employees, key agents of EEH and its wholly owned or controlled subsidiaries, the Edward Hospital, Linden Oaks Hospital, Elmhurst Memorial Hospital Medical Staff officers, and certain Providers as defined by this policy. Defined terms shall have the meaning set forth in the Definition section of this Policy.

A Conflict of Interest can occur when a person has a private interest that an independent observer might reasonably determine unduly influences (consciously or unconsciously) their professional obligations of acting on behalf of and for the benefit of EEH and the care of its patients.

This policy requires that Interested Persons report potential Conflicts of Interest arising from Financial or Business interests held by them or their Immediate Family members, as well as other situations that are material to the existence of a Conflict of Interest. If an actual Conflict of Interest is determined to exist or a relationship may be perceived as such, the conflict will be addressed through compliance with an identified conflict management plan unless the issue or circumstances cannot be adequately managed

or if it is inconsistent with EEH's Conflict of Interest Guiding Principles (see Exhibit C).

Conflicts of interest can arise in the context of clinical care and in the context of EEH's relationship with Industry, including decisions made by employed Providers and PSA Providers. Specific situations that arise in connection with clinical care are covered under Exhibit A – Relationships with Industry. Exhibit A only applies to employed Providers and PSA Providers. It does not apply to independent healthcare providers. Conflicts of Interest may also arise in the context of clinical research. Due to the special nature of these circumstances and the regulatory framework applicable to that activity, EEH has a separate policy that addresses these matters – see RSCH_019 "Investigator Conflicts of Interest in Clinical Research".

Definitions:

PSA PROVIDER: A physician or allied health professional subject to a Professional Services Agreement whereby EEH is billing for the professional services provided by the Provider.

BUSINESS: Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes, and which engages or attempts to engage with EEH or which is a direct competitor of EEH.

BUSINESS INTEREST: Holding any position with a Business, such as employee, officer or director on a board, including an advisory board, regardless of compensation.

CONFLICT OF INTEREST STATEMENT: All Interested Persons shall be required to complete and submit a Conflict of Interest Statement on an annual basis in accordance with this policy.

CONTRIBUTION: A donation of any property, tangible or intangible, to an EEH entity, including the Edward Foundation or the Elmhurst Memorial Foundation.

DISCLOSURE: The act or process of making information available to a third party such as a patient regarding the existence of a Conflict of Interest.

FAIR MARKET VALUE: The price at which property or services, or the right to use property or services, would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell, or transfer property or services or the right to use property or services, and both having reasonable knowledge of relevant facts and without regard to the volume or value of referrals generated between the parties.

FINANCIAL INTEREST: An ownership or investment interest in a Business and/or a Compensation relationship with 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 not 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.

INDUSTRY: A person or entity (or an entity controlled by, or under common control with, such a person or entity) that manufactures, distributes, or otherwise provides a Product or Service.

IMMEDIATE FAMILY: Shall include the following relatives of the Interested Persons: spouse or domestic partner, dependents and children (whether natural or adopted), ancestors, grandchildren, great-grandchildren, brothers, and sisters (whether by whole or half-blood) and the spouses of any foregoing relatives.

INSIDE INFORMATION: Material information concerning the issuer of a publicly-traded security that has not been made available to the general public.

INTELLECTUAL PROPERTY RIGHTS: Property (as an idea, invention, or process) that derives from the work of the mind or intellect.

INTERESTED PERSON: The following individuals associated with EEH and its wholly owned or controlled subsidiaries shall be required to disclose actual, apparent or possible Conflicts of Interest in accordance with this policy, and shall be referred to as "Interested Persons" for purposes of this policy:

- (a) all members of the Board of Trustees and all officers of EEH;
- (b) all members of the EEH Management Team or Management Council;
- (c) all Providers who are compensated by EEH as employees or independent contractors, including but not limited to physicians who have been retained or employed as Medical Directors or Medical Advisors;
- (d) all PSA Providers;
- (e) all members of the Medical Staff who participate or may participate in purchasing recommendations such as the members of the Pharmaceutical and Therapeutics Committee, medical directors, etc.;
- (f) the Edward Hospital and Elmhurst Memorial Hospital Medical Staff Presidents;
- (g) those employees and agents of EEH and each affiliate which are so designated by the President/CEO of that affiliate;
- (h) any EEH employee who has a Financial Interest, at such time when that Financial Interest arises.

Disclosures shall be made whenever the actual, apparent or possible conflict occurs in accordance with the first paragraph of the "Reporting, Review and Governance" section of this policy. In addition, these individuals shall be required to complete and submit a Conflict of Interest Statement on an annual basis in accordance with the "Reporting, Review and Governance" section below.

PRODUCT: A medical device, implant, pharmaceutical, other health-related product or software recommended, prescribed or utilized in patient care.

PROFESSIONAL ORGANIZATION: A non-profit organization seeking to advance a particular profession, the interests of individuals engaged in that profession, and the public interest.

PROVIDER: A physician or allied health professional.

REPORTING: The act or process of making information available to EEH regarding a potential Conflict of Interest.

SERVICE: Supplying or performing a service related activity or function that may be recommended, prescribed or utilized in patient care.

Procedure:

COMPLIANCE

Interested persons shall comply with all applicable government statutes, ordinances and regulations related to Conflict of Interest. This policy is subject to and consistent with EEH's bylaws including for its subsidiaries (see Exhibit B).

Without limiting the provisions of this policy, no EEH entity shall enter into any contract or transaction involving an Interested Person except in accordance with Illinois General Not-for-Profit Corporation Act of 1986, 805 ILCS, 105/108.60 "Director Conflict of Interest" as now enacted or amended from time to time.

DEFINITION OF CONFLICT OF INTEREST

A Conflict of Interest is 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). When determining if a Conflict of Interest exists, EEH will also consider whether the perception of a conflict exists and whether such perception is sufficient to support a finding of an actual Conflict of Interest. Situations which may create a Conflict of Interest, include, but are not limited to, the following transactions involving an Interested Person in his or her relationship to EEH:

- a. Sale, purchase, lease or rental of property.
- b. Rendering of services.
- c. Engagement in competing activities.
- d. Consulting on matters involving an Interested Person's role and responsibility within EEH and/or utilizing data or information which are proprietary in nature.
- e. An interest in any enterprise seeking to establish business relations with EEH.
- f. Acceptance, directly or indirectly, of any money, gift or object of value from any person or enterprise which has or is seeking business with EEH which may affect, or appear to influence judgment.
- g. When an organization with which an Interested Person is associated solicits a grant from the Edward Foundation, the Elmhurst Memorial Foundation or other EEH entity.
- h. Conflict of commitment.

A Conflict of Interest does not arise solely because a contract or other transaction or matter exists with EEH. A Conflict of Interest arises solely because of the nature of an Interested Person's professional obligations. Moreover, an Interested Person who has a Financial Relationship or Business Interest with respect to one or more legal entities within the EEH System has such interest with respect to all EEH entities.

PROHIBITED ACTIVITIES

1. Interested Persons may not engage in the following activities with respect to Business or Industry
 - (a) Acceptance of gifts influencing decision-making. Gifts, favors, services, entertainment or other things of value to the extent that decision-making or actions affecting EEH might be influenced, or appear to be influenced are prohibited.
 - (b) Solicitation from an actual or prospective customer (e.g., patient, provider, payor, or supplier of EEH) of any compensation, advance, loans, gifts, entertainment or other favors or personal benefit of any kind. Note: This provision is not intended to preclude the Foundations from seeking sponsors for their fundraising activities.
 - (c) Subject to fraud and abuse laws, self-referral prohibitions, and anti-kickback laws applicable to business relationship with government contractors, Interested Persons may accept discounts on a personal purchase of a supplier's or customer's products only if such discounts do not affect EEH's purchase price and are generally offered to others having a similar business relationship with the supplier or customer.
2. No Interested Person may receive free or discounted medical care at any EEH facility, except as part of his or her regular health insurance program or EEH policy. EEH has various policies which provide for free or discounted medical care in certain circumstances.
3. Interested Persons, who due to their position with EEH possess Inside Information regarding an investment may not purchase or sell such investment or engage in speculative trading in connection with such investment, either directly or through an account over which they have discretion (whether or not for their direct or indirect benefit), and may not communicate Inside Information to another person, other than on a lawful need to know basis. Interested Persons shall advise Immediate Family members as appropriate that confidential information received from an Interested Person

may not be used in connection with the purchase or sale of any investment and that trading on the basis of inside information is improper. In addition to third parties doing business with EEH, this provision also applies to trading of EEH's own financial instruments, such as its tax-exempt bonds.

ACCEPTABLE ACTIVITIES

Interested Persons may (see Exhibit A for more guidance regarding relationships with Industry for Providers):

1. Accept reasonable food and beverages offered to all participants during on-site or off-site educational presentations or sessions.
2. Accept modest meals and beverages incidental to a bona fide business meeting.
3. Provide modest gifts, meals and beverages to third parties that are doing or may be doing business with EEH.
4. Accept meals or refreshments at the vendor's expense. Occasional attendance at a local theater or sporting event, or similar entertainment at the vendor's expense may also be accepted. In most circumstances, a regular business representative of the vendor should be in attendance with the employee.
5. Engage in a consulting relationship with Industry for services when the following conditions are met:
 - (a) There is a legitimate need for the services provided.
 - (b) Services are provided pursuant to a signed, written agreement, established in advance and providing a description of the services, deliverables, time period, compensation and that the Interested Person is acting solely in his or her individual capacity and not as an agent or representative of EEH.
 - (c) The compensation is consistent with Fair Market Value.
 - (d) Compensation may include reimbursement for reasonable and actual expenses such as travel, meals and lodging.
 - (e) Consulting agreements are entered into by Interested Persons individually, and EEH assumes no liabilities or obligations, express or implied, under any agreement between an Interested Person and Industry. Any review of a consulting agreement by EEH is done for purpose of Conflict of Interest review and not for purposes of legal or other review for the Interested Persons.

REPORTING, REVIEW AND GOVERNANCE

Reporting Potential Conflicts of Interest

Financial and Business Interests that create a potential Conflict of Interest and must be reported are:

- 1) Compensation. All compensation, regardless of amount, received from one or more Business entities in the calendar year preceding reporting or anticipated during the calendar year. Compensation includes salary and payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, and paid authorship).
- 2) Ownership or Investment Interests. All Interested Persons are required to report the dollar value of all Ownership or Investment Interests in public or privately-held Business organizations, if the Interested Person had or is expected to have a direct or indirect involvement in the decision to engage that organization or play any role in the management of EEH's relationship with it.
- 3) Royalties paid in connection with any EEH Intellectual Property Rights as they may arise such as patents and copyrights, including agreements to share in royalties related to such rights.
- 4) Business Interests or potential Business Interests including holding any position, such as employee, officer or director on a board, including an advisory board of a Business entity, regardless of compensation must be reported.
- 5) Other. Any other relationships or interests that a reasonable person would deem material to the question of the existence of a Conflict of Interest.

Conflicts of commitment must also be disclosed. Conflicts of commitment may occur when an individual has professional obligations or potential professional obligations outside of EEH.

- 1) Professional obligations outside of EEH. Must be disclosed when they are in the same subject matter area as the individual's EEH employment responsibilities. They must occur on an individual's personal time.
- 2) Potential professional obligations outside of EEH. When as a result of his or her relationship to EEH, an Interested Person becomes aware of a business opportunity that could benefit the Interested Person (or their Immediate Family member), the Interested Person must first present the opportunity to EEH if in his/her best judgment the opportunity would be of benefit to EEH. Only after EEH decides not to pursue the opportunity, may the Interested person pursue the matter for his or her own account or benefit of others. Even then, the Interested Person should not pursue the opportunity if it will not permit the Interested Person to fulfill his or her obligations to EEH.

Reporting is not required in the following circumstances:

- 1) Income from seminars, lectures, or teaching engagements sponsored by governmental or government-sponsored agencies or by non-profit entities organized solely for educational, religious, philanthropic, or research purposes (with the exception of non-profit entities created by for-profit corporations).
- 2) Income when serving as a special reviewer or review panelist for a public (governmental) or nonprofit entity.
- 3) Income from services provided to professional organizations.

All Interested Persons are required to report potential Conflicts of Interest to the Compliance Officer in accordance with this policy when the Interested Person reasonably believes his/her circumstances could be creating a Conflict of Interest, or prior to their arising, so that EEH can proactively review the report to identify actual and potential Conflicts of Interest; in addition, certain Interested Persons, such as members of the Board of Trustees, Corporate Officers and other key employees will be provided with a Conflict of Interest Reporting Form annually, which shall be used for purposes of reporting potential Conflicts of Interest. All reports shall be prompt, full and frank, will identify the potential Conflict of Interest and will provide sufficient and relevant detail to adequately review the circumstances or issue.

Review and Oversight of Potential Conflicts of Interest

Subsequent to reporting, and depending on the nature of the matter, the Compliance Officer will review the reported information and may either arrive at a determination regarding the matter, or refer the matter as follows:

- To the Conflict of Interest Work Group (composed of the Compliance Officer, the General Counsel, Deputy General Counsel and Chief Financial Officer) for further deliberation. In certain cases, and especially where subject matter expertise is necessary, that Work Group may seek the assistance of a subgroup that may be formed for special purposes.
- For potential Conflicts of Interest involving members of the Board of Trustees, members of a subsidiary Board of Trustees and EEH senior executive personnel, the Compliance Officer will refer the matter to the Executive Committee for review and direction. That Committee may also delegate decisions relating to potential Conflicts of Interest by using EEH's *Guiding Principles for Conflict of Interest (see Exhibit C)*
- For potential Conflicts of Interest involving PSA Providers or employed Providers, the Compliance Officer will refer the matter to the Vice President, Physician and Ambulatory Network and the System Vice President, Physician and Ambulatory Network and the President of Linden Oaks Hospital as appropriate.

If the Compliance Officer, Conflict of Interest Work Group or the Executive Committee determines that a Conflict of Interest exists, appropriate mitigating or remedial measures may be taken through a management plan in consultation with the Interested Person.

Management plans are intended to maintain transparency and decrease perceptions of influence and may include, but are not limited to, monitoring or follow up on a particular relationship, disclosure to the individual patient, consultation with a colleague for a prescription where a Financial or Business Interest is involved, transfer of a patient to another provider or divestiture or modification of the relationship with

Business or Industry, if necessary.

If a management plan has yet to be developed and the Interested Person is involved in discussion related to his/her conflict, the Interested Person must disclose the Conflict of Interest to those involved in the conversation and must recuse him/herself from participating in the conversation and making a decision on behalf of EEH. If this conversation takes place at a Board meeting, the minutes of the meeting should reflect the fact that the Conflict of Interest has been disclosed and the Interested Person has recused him/herself.

If the issue or circumstances cannot be adequately addressed through a management plan or if the proposed or actual arrangement is inconsistent with EEH's *Guiding Principles for Conflicts of Interest* (see *Exhibit C*), the conflict will be eliminated.

Disclosure of the management plan may be made to appropriate individuals or committees, which may include patients, students, a department, group, or others as necessary. Monitoring and oversight of Conflicts of Interest and management plans will be conducted by the Conflict of Interest Work Group and the Executive Committee.

Enforcement

All Interested Persons are required to comply with the provisions of this policy and EEH's determination on matters related to resolving potential Conflicts of Interest. Such compliance is a condition of employment at EEH. In the event that an Interested Person does not comply with that determination, a review will be performed and appropriate corrective action may be taken, including retraining of the Interested Person, referral for further action, termination of employment, termination of the agreement with EEH, or removal from the Board of Trustees.

EXHIBITS:

EXHIBIT A RELATIONSHIPS WITH INDUSTRY

This Exhibit only applies to Providers within the scope of their employment or the scope of services provided under contract with the System.

A. Industry Visits to EEH

Visits by Industry representatives must occur according to EEH policies and procedures. These policies include that Industry representatives visiting Edward Hospital, Elmhurst Memorial Hospital, Linden Oaks Hospital, Edward Medical Group, Linden Oaks Medical Group or an Elmhurst PSA Practice must be certified according to the vendor certification programs in place at those organizations and comply with the requirements in those programs.

Access by pharmaceutical and device representatives to individual Providers should be restricted to non-patient areas and non-public areas and should occur only by appointment or invitation of the Provider or other appropriate person. Only EEH-certified and approved pharmaceutical or medical device Industry representatives should have access to patient care areas and this should occur only by appointment or invitation of the Provider.

B. Educational Events and Activities including Speaking Engagements

1) Attendance at Educational Events

Providers may attend Industry-sponsored educational presentations or sessions (see 4.

below for a discussion of speaking engagements). Such educational presentation or session must meet Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Graduate Medical Education (ACGME) and/or other similar standards for educational content, which include that the content or format and related materials must promote improvement and/or quality of healthcare and not a specific proprietary business interest of a commercial entity and must give a balanced view of therapeutic options. Providers may accept modest food and beverages offered to all participants during these on-site or off-site educational presentations or sessions.

Providers must pay for any costs required to attend these educational events, including meeting registrations, travel, lodging, and related expenses. Free educational events that otherwise meet the requirements of this policy are acceptable. For EEH-employed Providers, payment or reimbursement by EEH for such educational events must be approved in accordance with EEH policies.

Providers may accept non-branded educational materials provided by Industry at educational events, but any branded Product or Service-specific materials may not be used within EEH facilities except in the context of patient education as identified in this policy.

2) EEH or Industry Sponsored Product or Service Specific Training

Providers may participate in Product or Service-specific training necessary for the safe and effective use of a Product or Service in patient care such as FDA-mandated training.

Where objective reasons support the need for out of town travel for such training, travel and related expenses associated with such Product or Service specific training must be approved in advance according to EEH policies.

3) Industry Funding of Educational Events/Activities

Industry funding for EEH-sponsored educational events must be in the form of an unrestricted grant, i.e. unrestricted with respect to the content or format of activities for which it may be used, and provided to the appropriate EEH entity or group.

4) Speaking Engagements

Providers may pursue speaking engagements or otherwise present at educational events when such events meet ACCME, ACGME, FDA PhRMA and/or other standards for educational content, including, but not limited to: 1) the event is designed to provide evidence-based medical information; 2) the Provider prepares the content, without any approval by Industry or the content is approved by the FDA; 3) the content reflects a balanced assessment of medical information and is not focused on a particular Product or Service; and 4) the Financial relationship(s) is disclosed during the speaking engagement per ACCME/ACGME standards.

Payments and expenses for these activities must also meet ACCME/ACGME educational standards and/or other educational standards. Such speaking engagements should also meet the standards for a consulting relationship, as defined in the Conflict of Interest Policy (Acceptable Activities) and are subject to the reporting and collaboration requirements in this policy and any related policies.

C. Patient Education Materials

Providers may accept and use general patient education materials from Industry when the materials are not branded by Industry and do not contain manufacturer-specific data or information.

Providers may accept and use branded materials when necessary to teach and solicit informed consent from a patient when the Product or Service is identified and utilized for the care of the patient. Industry educational materials should follow ACCME/ACGME and/or other generally

accepted medical standards for educational materials.

D. Samples, Supplies, and Equipment, Including Free or Discounted Products or Services

1) Pharmaceutical or Other Samples

The storage and use of drug samples for the treatment of inpatients is prohibited. Drug samples may be dispensed for home use to patients if deemed appropriate by the prescriber. Samples may be used at designated outpatient sites, and the site is responsible for the control and storage of the drug samples.

2) Trials of Supplies and Equipment

EEH supports innovation and best practice. When Providers wish to evaluate new supplies or equipment, discounted or no-cost supplies or equipment may be provided by Industry for evaluation. For supplies or equipment that have, or may have the potential of having, a substantial effect on patients, the items should be approved by EEH, including its Value Analysis Team regardless of the cost of the supplies or service.

E. Medical Missions or Other Charitable Activities and Contributions

Consistent with its mission to improve the health of the community it serves, EEH supports charitable activities such as medical missions and other charitable activities such as free- or low-cost clinics. Contributions must be motivated by bona fide charitable purposes, must only be made to bona fide charitable organizations or in rare instances to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission and must be approved by EEH management. EEH must exercise due diligence to ensure the bona fide nature of the charitable organization or charitable mission. Pharmaceuticals or other Products or Services from Industry may be donated to these charitable activities or facilities. Such donations may not be stored in any EEH site, unless approved by EEH.

F. Decision-Making Relative to Product or Service Purchase

When a Provider has a Financial or Business interest with Industry, the Provider may provide relevant clinical information but shall not participate in a decision or vote related to the use, purchase or recommendation of the Product or Service by EEH. The Financial or Business Interest should be disclosed to the particular committee or other group involved with the Product or Service purchase according to EEH policies and/or process applicable to technology assessment.

G. Financial and Other Relationships with Industry

Under appropriate circumstances, Providers or their Immediate Family Members may have a Financial or Business interest with Industry if the interest or relationship does not reasonably affect the Provider's recommendation or use of the Industry's Product or Service. Employed Provider's or their Immediate Family Member's Financial or Business Interest with Industry must be approved by EEH management.

Such interests and relationships must be reported and reviewed according to this Policy (See Reporting Potential Conflicts of Interest). These interests or relationships must be designed so they do not constitute "Prohibited Activities" as defined in this Policy.

H. Other Prohibited Activities

Providers may not accept the following items offered or provided by Industry or engage in the following activities involving such entities at any time, regardless of whether the interaction or activity occurs in an EEH facility or at a facility in which EEH is contracted to provide patient care, unless the activity is covered by a lawful waiver (e.g., an Accountable Care Organization waiver).

- Payments or other benefits intended to influence the volume or value of patient referrals.
- Payments or other benefits intended to influence prescribing practices or medical decision-making, or based on or solely related to consideration of or a decision to use a

Product or Service.

- Payments or other benefits for switching arrangements to change the use of a Product or Service from the current/competing Product or Service to another Product or Service or another health care entity or other entity.
- Payments or other benefits to recruit patients for clinical research activities except recruitment activities approved by the appropriate Institutional Review Board (IRB).
- Payments or other benefits for attendance or involvement at conferences including associated travel expenses, except when speaking or presenting per a legitimate consulting relationship, as defined in this policy.
- Payments or other benefits for attending, reviewing or listening to medical education programs (i.e., not speaking or actively presenting) or viewing or reading web sites, books, or other information materials unless pursuant to a legitimate consulting relationship as defined in this policy.
- Ghostwriting which includes, but is not limited to, a publication or similar document created by Industry and not written or drafted by, but attributed to a Provider.
- Payments or other benefits for completing Product or Service evaluations or surveys for Industry, including when EEH is also evaluating the Product or Service, unless an evaluation or survey is done pursuant to a legitimate consulting relationship as defined in this policy.

EXHIBIT B EEH BYLAWS

Section 3.8 Conflict of Interest

- (a) Any possible Conflict of Interest on the part of a Trustee or an Officer shall be disclosed to the Board of Trustees. When any such interest relates to a matter on which action is to be taken by the Board of Trustees, such Trustee shall not take part in the deliberations of, vote or use personal influence on the matter, and shall not be counted in the quorum for a meeting at which action by the Board of Trustees is to be taken. The Trustee may, however, answer pertinent questions of members of the Board of Trustees. The minutes of all actions taken on such matters shall clearly reflect that these requirements have been met.
- (b) Each Trustee and each Officer shall be required to complete an annual Conflict of Interest questionnaire. Failure to complete the questionnaire in a timely manner shall constitute cause for removal of a Trustee or an Officer, should the Board of Trustees so determine to act.

EXHIBIT C GUIDING PRINCIPLES FOR CONFLICTS OF INTEREST

Edward-Elmhurst Healthcare (“EEH”) has developed a set of two conflict of interest (COI) policies including: (1) Conflict of Interest; and (2) Investigator Conflicts of Interest in Clinical Research.

These policies are important to establish expectations of EEH’s commitment to compliance with the law, regulations and rules. Just as importantly, EEH has developed underlying Guiding Principles related to the policies so that one might understand the “spirit” of the policy especially when facing situations not specifically addressed by the policies. These Guiding Principles have been developed to help address EEH’s philosophical approach to COI’s; its governance processes in overseeing COI’s; and the expected behavioral standards applying to its Board of Trustees and all employees.

Philosophical Approach

EEH's mission is "to support health and strengthen communities by providing outstanding healthcare services" and its vision is "Locally responsive, Regionally significant health system." Central to the mission and vision is patient care and the health of the community we serve which will require greater levels of innovation and partnership. EEH recognizes that resulting relationships may, from time to time, pose conflicts of interest. EEH will proactively identify and manage potential and actual conflicts of interest unless they are inconsistent with its Conflict of Interest Guiding Principles and Policies.

Governance Process

Oversight and management of conflicts of interest utilizes an intensive process including the following steps: (1) conflicts of interest are proactively reported; (2) appropriate reviews will be conducted; (3) depending on the nature of the conflict the reviews will be conducted by the Compliance Department, COI Work Group, and/or the Executive Committee of the Board of Trustees; (4) implement a robust plan to manage the conflict; or (5) eliminate the conflict if it is inconsistent with the COI Guiding Principles and Policies and cannot be appropriately managed; and (6) provide transparency to the affected audiences.

Guiding Principles

Central to our relationship with our patients, the public and our partners is integrity. When faced with conflicting interests, to preserve integrity, we are guided by the following principles:

- The health of our patients and the community comes first and precedes organizational or individual gain;
- We act with integrity openly and honestly disclosing our actions;
- Conflicts must be reported; the nature of the conflict identified; and if permitted, actively managed;
- Stewardship: We appropriately utilize resources and always act in a way that preserves public trust;
- Laws and Regulations: Always comply with both the "letter" and the "spirit" of the law

EXHIBIT D

CONFLICT OF INTEREST IN RESEARCH DISCLOSURE, REVIEW AND GOVERNANCE

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 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 subpart reflects the purpose of 42CFR§50, Subpart F: Promoting Objectivity in Research (commonly known as the Financial Conflict of Interest (FCOI) regulations) in that it promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from Investigator financial conflicts of interest. This policy also reflects the requirements set forth in 21 CFR part 54 related to financial disclosures by clinical investigators for new drug and medical device applications to the Food and Drug Administration (FDA).

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

This policy subpart is intended to supplement and not circumvent other policies adopted by EEH; however, in the event of conflict, this policy shall supersede on matters related to Investigator conflicts of interest in clinical research.

EEH shall conduct on-going monitoring of compliance with the above EEH policy, this policy subpart and applicable federal, state, and local laws and regulations governing clinical research. This policy subpart shall be publically available on the EEH website.

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.

FCOI Report: EEH's report of FCOI that is sent to a PHS Awarding Component.

FDA: U.S. Food and Drug Administration

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.

Immediate Family: the spouse and dependent children of an Investigator.

Institution: Edward-Elmhurst Healthcare.

Institutional Official: the executive designated by EEH as the Signatory Official on the the EEH Federal-wide Assurance.

Institutional Responsibilities: an Investigator's professional responsibilities on behalf of the Institution, as these responsibilities may be further defined in this policy. Institutional Responsibilities may include, for example, activities such as clinical service, research, research consultation, administrative management, education, professional practice, and institutional committee and board memberships, including service on the EEH Institutional Review Board and the EEH Institutional Research Oversight Committee.

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 EEH may contract with to carry out a Clinical Study.

IRB: the EEH Institutional Review Board.

Manage: 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 Clinical Research will be free from bias.

Research Conflict of Interest Committee ("RCOI Committee"): the committee designated by EEH to determine if a Significant Financial Interest that is related to a proposed or ongoing Clinical Study constitutes a Conflict of Interest, and to approve any plans to Manage a Conflict of Interest.

Research Integrity Officer ("RIO"): the person designated by the EEH 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 EEH IRB; or (ii) contractually or otherwise affiliated with EEH for the purpose of engaging in Clinical Research, including subcontractors or Subrecipients.

Senior/Key personnel: Investigators and any other person(s) identified by the Institution as Senior/Key personnel who are essential to the performance of the research project in the grant application, progress report or any other report submitted to the PHS or FDA.

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 EEH 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.

Sponsor: any person or entity that initiates, funds, or otherwise supports the Clinical Research, including the PHS, or an owner, patent-holder, license holder or other controller of the drug, device, biologic or treatment that is the subject of the Clinical Study.

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Procedure

A. 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. The System Director of Internal Audit and Compliance or designee shall email the electronic COI questionnaire to each Investigator requesting completion of a Conflict of Interest Statement in accordance with the following schedule:
 - i. At the commencement of a new funded study.
 - ii. At least annually while a funded study is being conducted at a Research Site;
 - iii. During the conduct of the Clinical Study, within thirty (30) days of discovering or acquiring (i.e. through purchase, marriage, or inheritance) a new Significant Financial Interest or any change in any prior reported information; and/or
 - iv. At the request of the RIO or RCOI Committee.
- b. When completing the electronic COI, each Investigator is required to include electronic files as an attachment for each Significant Financial Interest or other Significant Financial Interests. This includes but is not limited to copies of any contracts, sponsor agreements, grants, leases, licensing agreements, corporate organization documents, equity subscriptions agreements, equity option agreements, stockholder agreements, and/or documents setting forth the current or potential terms of any Significant Financial Interest or other Significant Financial Interest.

B. Conflict of Interest Review:

- a. Collection and Assessment
 - i. The Corporate Compliance Coordinator shall collect a Conflict of Interest Statement and any associated or additional documents, from each Investigator in accordance with the above schedule.
 - ii. The Corporate Compliance Coordinator shall review each Conflict of Interest Statement for completeness, and may request that the Investigator submit additional documents or statements in order to accurately describe any Significant Financial Interests or other Significant Financial Interests.
 - iii. Upon receipt of all necessary documentation, the Compliance Coordinator will work with the System Director of Internal Audit and Compliance to review, adjudicate, and manage (when applicable) a disclosed Significant Financial Interest or other Significant Financial Interest that could reasonably be related to Clinical Research

C. Actions to Manage, Reduce or Eliminate Conflict of Interest. If it is determined that an Investigator has a Conflict of Interest, a plan to manage the Conflict of Interest will be determined in accordance with this policy. Examples of conditions or restrictions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:

- a. Requiring public disclosure of the Conflict of Interest (e.g., when presenting or publishing the research; to staff members working on the Clinical Study; and to the EEH Institutional Review Board);
- b. Disclosing the Financial Conflict of Interest to the human subjects participating in the Clinical Study;
- c. Requiring modification of the Clinical Study plan;
- d. Change of Investigator responsibilities, or requiring disqualification of the Investigator from participation in all or a portion of the Clinical Study;
- e. Requiring divestiture of the Investigator's Financial Interest;
- f. Requiring severance of the Arrangement between the Investigator and the party(s), including the Sponsor, that creates the actual or potential Conflict of Interest;
- g. In the case of PHS funded studies, reporting the Conflict of Interest to the PHS Awarding Component; or
- h. Take such other action that the RCOI Committee determines to be appropriate.

D. Notice of Action.

- a. Following determination of the appropriate management plan, the System Director of Internal Audit and Compliance or designee shall provide the Investigator, the IRB of record, and/or Sponsor with a written determination and the actions that must be taken by the Investigator to manage, reduce, or eliminate a Conflict of Interest.

E. Violations of the Conflict of Interest Policy

- a. If there is reasonable cause to believe that an Investigator has failed to disclose information on an actual or potential Conflict of Interest, the RIO shall immediately inform the Investigator of the basis for such belief and afford the Investigator an opportunity to explain the alleged failure to disclose or comply.
- b. If the RIO determines that the Investigator has failed to disclose meaningful information on an actual or potential Conflict of Interest, then the RIO shall immediately notify the Institutional Official.
- c. If the RIO determines on evaluation that the Investigator has failed to comply with instructions on managing, reducing or eliminating the Conflict of Interest, the RIO shall:
 - i. Immediately notify the Institutional Official, who shall take such administrative, contractual or personnel actions as are necessary to address the violation of this Policy, including suspension or termination of the conduct of the Clinical Study and/or any applicable contract;
 - ii. Develop and implement, on an interim basis, a management plan that shall specify the action that has been or will be taken to Manage the Conflict of Interest going forward;
 - iii. Notify the IRB of record so they may take actions necessary to protect the integrity of the data and the safety of the human subjects participating in the Clinical Study in a manner consistent with this Policy; and
- d. If any EEH employee has reasonable cause to believe that (i) a Conflict of Interest has not been identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined by the RCOI Committee to constitute a Conflict of Interest, or (ii) failure by the Investigator to comply with a Conflict of Interest management plan, the System Director of Internal Audit and Compliance shall:
 - i. Within a reasonable amount of time of EEH 's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Clinical Study to determine whether the Clinical Study, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
 - ii. Document the retrospective review, which shall include the following elements: (1) Project number; (2) Project title; (3) Name of the Principal Investigator of the Clinical Study; (4) Name of the Investigator with the Conflict of Interest, (5) Name of the entity with which the Investigator has a Conflict of Interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed), (8) Findings of the review; and (9) Conclusions of the review.
 - iii. Based on the findings of the retrospective review, if appropriate, EEH shall update any previously submitted FCOI Report, specifying the actions that will be taken to manage the Conflict of Interest going forward, EEH may determine that additional interim measures are necessary with regard to the Investigator's participation in Clinical Study sponsored by PHS between the date that the Conflict of Interest or the Investigator's noncompliance is determined and the completion of the EEH's retrospective review.

Enforcement Mechanisms

In the event of an Investigator's non-compliance with this policy EEH may implement a range of enforcement mechanisms, including but not limited to suspension or termination of a Clinical Study; suspension or termination of research privileges; dismissal from IRB or other board or committee membership; discipline under EEH's employee disciplinary policies, if applicable, and/or termination for cause of any contract, agreement or award. Violations of federal or state statutes and guidelines shall be handled consistent with federal and state laws and requirements.

CROSS REFERENCE(S)

Policy Committee Review:	Effective Date:	Current Policy Replaces Policy:
October 7, 2014		Edward GENL_006 – Conflicts and Dualities of Interest
		Elmhurst Conflicts and Dualities of Interest
Board of Trustees 10-21-14	October 21, 2014	
9-29-2015 – Annual Review no changes	November 6, 2015	
1-05-2016 (added Exhibit D)	January 29, 2016	