OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH

GUIDANCE #3

Additional Requirements for Identifying and Reporting Conflicts of Interest

1. **Overview**
   This guidance is to allow applicable individuals to identify and report conflicts of interest. These procedures apply to all clinical research activities approved by the Office of Human Subjects Research within the Hennepin County Medical Center campus.

2. **Applicable Regulations and Guidelines**
   21 CFR 54
   21 CFR 312
   21 CFR 812
   42 CFR 50
   45 CFR 94
   Hennepin Healthcare Research Institute Conflict of Interest Policy (01/2016)

3. **Applicable Guidance Attachments**
   Hennepin Healthcare Research Institute Conflict of Interest Policy (1/2016) Report of External Professional Activities
   Application for External Support
   HHRI Conflict of Interest Mitigation Plan Development Outline

4. **Applicable Personnel**
   Principal Investigator
   Sub-Investigator
   Research Team Members

5. **Procedures**
   The outlined procedures are designed to implement the Hennepin Healthcare Research Institute (HHRI) Conflict of Interest Policy in a manner that ensures that conflicts of interest do not adversely affect the protection of research participants, the integrity of the research conducted on the Hennepin County Medical Center campus, or the credibility of the Human Subjects Research Committee (HSRC).
   A. Disclosure Procedures
      i. The HHRI Conflict of Interest (COI) Policy considers all of the applicable personnel listed above to be "Covered Persons." The HHRI COI policy and disclosure reporting requirements are communicated to all "Covered Persons" upon initiation of their employment or engagement as an agent of the HHRI, annually, and as soon as possible after any changes are made to the policy. The HHRI COI Policy is also available on the HHRI website.

ii. The HHRI COI Policy sets no minimum threshold for disclosure – all external relationships must be reported at least annually, and any relationships that constitute the potential for a conflict of interest must be reported **prior to their initiation**. The methods and associated timing of reporting external relationships is outlined below.

Form	Completed by	Frequency	Recipient
Report of External Professional Activities	All Covered Persons	Annually	Chief Operating Officer
Application for External Support (includes Compliance Committee Standardized Reporting Form questions)	All "Key Personnel," defined as any individual in a position to influence the design of the research, its conduct and reporting.	Upon submission of external proposals	Office of Grants and Contracts
Compliance Committee Standardized Reporting Form	All "Key Personnel," defined as any individual in a position to influence the design of the research, its conduct and reporting.	Upon submission for approval and upon change in Key Personnel	Human Subjects Research Committee
Ad Hoc Written Communication	All Covered Persons	Immediately upon a change in external financial relationships affecting an active project	Chief Operating Officer

iii. Any positive disclosures received by either the HSRC or the Office of Grants and Contracts (OGC) are immediately forwarded to the Assistant Vice President of Operations, who notifies the Chief Operating Officer (COO) and coordinates with the Conflict of Interest Committee. The status of disclosed conflicts that are under review is monitored on a shared report that is coordinated by the OGC, thereby ensuring that no HSRC approval letters or account numbers are released until all conflicts are either resolved or appropriately managed under the direction of the COI Committee.

B. COI Committee Procedures

i. Not all external financial interests are considered Significant Financial Interests (SFI) and not all SFIs are considered conflicts of interest. The HHRI COI Policy sets no arbitrary threshold for determining that a conflict of interest exists to allow the COI Review Committee to retain the prerogative for making such judgments based on the unique facts and circumstances of each situation. However, in no event is an interest of greater than $5,000 considered "not significant," and all disclosures of greater than $5,000 are reviewed by the full COI Committee. Financial interests of less than $5,000 may be reviewed by the HHRI Conflict of Interest Chairperson, HHRI President and VP/COO or another member of the COI Committee.

ii. Factors that are taken into consideration when evaluating disclosures include (but are not limited to):

a. Whether an interest is significant

b. Whether an interest poses an increased risk to research subjects

c. Whether the interest poses any risks to the scientific integrity of study design, data collection, analysis and reporting

d. Expected benefits of the activity

iii. Deliberations regarding conflict evaluation and the appropriateness of proposed mitigation plans are documented in COI Committee minutes, which are maintained by the COO's office. Conflict management procedures may include retrospective review of data produced, monitoring of publications, or a formal mitigation plan if the conflict is not resolved by ending the relationship that creates the conflict.

iv. The COI Committee is the entity that determines if a Conflict Mitigation Plan is necessary, and whether a proposed Conflict Mitigation Plan is appropriate. Acceptable conflict mitigation can take many different forms, but in general must include some sort of separation between the conflicted investigator and the data collection, data analysis, and publication of a project. A template mitigation plan is included in the Appendix to this Guidance. The COI Committee membership includes members of the HSRC which means decisions regarding Conflict Mitigation Plans include considerations related to the protection of human research subjects.

v. In the event of non-compliance of a covered person with any determinations of the COI Committee, enforcement mechanisms may include employee sanctions, (including but not limited to) suspension of HSRC project approval, suspension of expenditure incurrence authorization, or deferral from the HSRC to consider any additional research submitted for review by the non-compliant covered person.

C. Grant Administration COI Procedures

i. The OGC maintains a database of all disclosed conflicts that tracks the details of the disclosure, including the date disclosed, the Principal Investigator name, the conflicted investigators name, the Sponsor name and type of organization, the Project Title, the nature of the conflict, and the Status. The status category includes date fields to ensure that any required agency reporting is completed in a timely manner and as required by the sponsored award terms and conditions.

This tracking tool is available on a secure shared drive so all affected and relevant HHRI divisions (HSRC, OGC, Chief Operating Officer, and COI Chairperson) can access the information as needed to exercise their monitoring responsibilities. This shared tool ensures that no expenditures are incurred, or HSRC approvals released, until all conflict disclosures are received, reviewed, and resolved or managed, and that all required agency reporting is completed appropriately. In the event that a conflict is disclosed on an existing project, this tracking tool also ensures that all reviews and reporting are accomplished in accordance with a sponsor's requirements.

ii. The HHRI Assistant Vice President of Operations is the person at the HHRI that ensures that the institution is fulfilling its reporting obligations to the appropriate agencies when it is required. The HHRI Assistant Vice President of Operations completes the annual Conflict of Interest reporting via NIH's eRA Commons, and when necessary, provides the information required to the specific federal agency when a conflict of interest on a federal study is identified.

iii. Documents related to a disclosed conflict on a sponsored project are maintained by the OGC, and kept with the related sponsored award files to ensure that the records are maintained in accordance with the sponsors' record-retention requirements. In all cases, records are retained for a minimum of three years from the completion of the research.

D. COI Training Procedures

All covered persons are required to complete training in COI in the course of completing the institutionally required CITI training (or equivalent) prior to engaging in any Human Subjects Research. Completion of this training is monitored by the Office for Education and Quality in Clinical Research (OEQCR) and HSRC via a shared database that requires verification that training requirements are satisfied before HSRC approval letters can be printed and released. No spending is allowed on projects involving human subjects unless required training is up to date. Per the HHRI training SOP, COI training is linked to CITI (or equivalent) training and must be completed at least every three years. Verification of training is provided from the OEQCR to the HSRC and the OGC via monthly reporting. Any researcher determined to be non-compliant with the institutional COI Policy or determinations of the COI Committee will be required to repeat COI training immediately upon notice of non-compliance.