UnityPoint Health Des Moines
Human Research Protection Program
Policy and Procedures for Managing Individual Financial Conflicts of Interest in Research

I. Policy

Individual financial conflicts of interest that may arise in the course of conducting basic, translational and clinical research at UnityPoint Health – Des Moines (must be identified, evaluated and managed.

II. Scope

This policy applies to all persons who perform, regulate or oversee research conducted under the auspices of UnityPoint Health Des Moines or an Institutional Review Board of this organization.

III. Relation to IHS Policy #20-003 on Conflict of Interest

This document is intended to supplement the policy and procedures set forth in UnityPoint Health Policy #20-003. The rationale for additional procedures beyond those described in #20-003 is that the general mechanisms for disclosing, evaluating, and managing conflicts of interest outlined in #20-003 may not suffice in situations arising in modern biomedical research, and especially in clinical research involving human subjects. As well, the scope of #20-003 is limited to UnityPoint Health employees, whereas the scope of this policy is broader and covers persons conducting research at UnityPoint Health Des Moines who may not be employees of the organization.

IV. Definitions

Covered Individual: Any person covered by this policy, namely all persons who perform, regulate or oversee research conducted under the auspices of UnityPoint Health Des Moines or an Institutional Review Board of this organization.

Disclosure: Release of relevant information about significant financial interests in research to institutional officials, and, as appropriate, to institutional review boards, research subjects or journal editors.

Immediate family: Spouse, and any family member who is dependent of the covered individual or whom the covered individual is dependent upon. A potential conflict of interest may arise when the party holding the financial interest is related to the employee in ways other than spouse and dependent children. Financial interests held

by this party should be disclosed by the covered individual to the best of his or her knowledge.

Significant Financial Interests in Research (SFI): A Financial interest consisting of one or more of the following interests of the Researcher (and those of the Researcher's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity of interest in the entity as of the date of the disclosure, when aggregated, exceeds $5,000. Remuneration includes salary such as consulting fees, honoraria, and paid authorships. Equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value.
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interest (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
- Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e.,, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value might not be readily available) related to the institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education. At a minimum, travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
- Service as an officer, director, or in any other fiduciary role for a financially interested company, whether remuneration is received for such service.

When following FDA regulations, significant financial interest of the researcher, research staff, or their immediate family means: Ownership interest, stock options, or other financial interest related to the research unless it meets the following four tests:

- Does not exceed $50,000 when aggregated for the immediate family,
- Publically traded on the stock exchange.
- No arrangement has been entered where the value of the ownership interest will be affected by the outcome of the research.
- Does not exceed 5% interest in any one single entity when aggregated for the immediate family.

Compensation related to research unless it meets the following two tests:

- Does not exceed $25,000 in the past year when aggregated for the immediate family.
- No arrangement has been entered where the amount of the compensation will be affected by the outcome of the research.

Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

Financial Conflict of Interest in Research (FCOI): A financial conflict of interest in research exists when the significant financial interest in research of a covered individual may compromise, or have the appearance of compromising, the covered individual's professional judgment in conducting or reporting research. Such a conflict can affect collection, analysis, and interpretation of data, as well as hiring of staff, procurement of materials, sharing of results, choice of protocol, recruitment and involvement of human participants, and use of statistical methods.

V. Principles of Managing Financial Conflicts of Interest in Research

A. Financial conflicts of interest in research require a robust management system.

The institution should have adequate procedures for identifying potential conflicts through annual disclosure and ensure rigorous and consistent review of such disclosures. The procedures should indicate how relevant officials (and in the case of clinical research, human participants) are to be informed of conflicts, and how those conflicts are to be managed. The institutions should sufficiently document conflict of interest decisions and monitor their implementation. Institutions should also ensure that policies, procedures, definitions, and sanctions for noncompliance are understood by all persons involved with research, including students and research participants. Finally, the institution should ensure intramural coordination on matters of conflict of interest management among the various offices involved.

B. Many financial interests are not conflicts, and many conflicts can be managed.

Given the complexity of financial relationships within the institution, the best way to handle many conflict of interest situations is on a case-by-case basis - to determine whether a researcher's financial interests are related to institutional research and constitute a conflict of interest, and if so, how the conflict should be managed. Many individual financial interests are not conflicts of interest in research, and many that *are* can be managed to avoid compromising research results or care of human participants. It may be determined that certain research should not be performed as originally proposed if the integrity of the research is to be maintained or research participants protected. The institution or the investigators must then decide whether to alter the protocol, divest a financial interest, or not undertake the research.

C. Research involving human participants requires special scrutiny
Since research involving humans creates risks that non-human research does not, any related financial interest in research involving humans should generally *not be allowable. If compelling circumstances justify an exception to this general* rule, the research should be subject to more stringent management measures (including disclosure to research participants) to ensure the integrity of the research and the safety of the human participants. The relationship between a researcher who may also be a healthcare provider and a research participant who may also be a patient is complex and places special responsibilities on the researcher to do no harm and to safeguard the human participant's welfare above all things.

D. Treat research consistently, regardless of funding source
All research projects, whether federally funded, funded by a non-federal entity, or funded by the institution shall be managed by the same conflict of interest process.

E. Disclose financial information to the institution
Covered individuals engaged in research should disclose on an annual basis all financial interests related to their research and provide updated information when new financial circumstances may pose a conflict of interest.

F. Disclose financial information to publications
When covered individuals engaged in research submit manuscripts for publication, they should disclose any financial interests they have which are related to the research.

G. Disclose financial information in oral presentations
Covered individuals should disclose to their audiences when presenting research results any financial interests that are related to the research on which they are reporting.

H. Disclose financial information to federal agencies
Federal regulations and policies require institutions using Public Health Service funds to report to the Department of Health and Human Services (HHS) the existence of conflicting interests found by the institution and to assure HHS that the institution has managed, reduced, or eliminated the conflicts prior to the expenditure of funding.

I. Disclose financial information in the human participant review process
Both conflict of interest processes and human participant protection systems have a role regarding conflict of interest: The Institutional Review Board has jurisdiction over determining whether a relevant financial interest (and how it is being managed, if

applicable) should be disclosed to human participants in research, and if so, in what form and detail.

VI. Procedures for Managing Financial Conflicts of Interest in Research

A. **Disclosure**

All covered individuals will disclose their financial conflict of interest in research annually, as individual circumstances change, and for investigators and research staff, with the submission of each new protocol application and each continuing review application. New significant financial interests must be reported to the IRB within 30 days of acquisition or discovery.

B. Standing research conflict of interest committee (RCOIC)

The RCOIC will consist of the UPHDM Corporate Compliance Officer (or designee); the Director of Organization Ethics; and at least one regular member of the Institutional Review Board. The committee will review all "Disclosure of Significant Financial Interest in Research" forms that contain individual disclosures, as they are submitted annually. The HRPP office will provide support for committee operations, including keeping minutes of RCOIC meeting minutes Following a meeting, RCOIC minutes will be included in the material sent to the IRB prior to the monthly meeting.

C. Matters to be considered by RCOIC

1. Annual disclosures: the RCOIC will evaluate disclosures submitted by covered individuals.

2. Disclosures made as individual circumstances change and an amended disclosure form is submitted to the HRPP office.

3. Disclosure made by a new investigator, research staff member, or IRB member at the time that the COI Disclosure form is submitted to the HRPP office.

In these cases, the RCOIC will determine whether the conflict does not require management, must be managed, or cannot be managed appropriately. All findings of RCOIC are transmitted to the IRB at the next convened meeting. The IRB is responsible for making the final determination of conflict of interest in each matter.

D. Disclosures made specific to study application

When disclosures are made at the time of new protocol application or continuing review application, or when a disclosure is made by a researcher with an open study, then the IRB will consider whether the conflict requires management. If the conflict requires management, a plan will be developed and approved at the convened meeting of the IRB.

E. Management of conflicts of interest

The Director of Human Research Protection, with the approval of the IRB, may direct the RCOIC to manage certain conflicts. Alternatively, the Director of Human Research Protection may appoint an ad hoc committee to manage a conflict; in such cases, at least one member of the RCOIC will sit on the ad hoc committee. Procedures for managing conflicts of interest will be based on the principles enumerated in the preceding section and may include:

- extensive interviews with investigators who are in conflicted situations;
- consultation with outside experts;
- detailed examination of files and documents;
- Management might include a retrospective review and mitigation report if necessary.
- All COI management plans will have the approval of the IRB.
- Management will include the required reporting to the research funding source or regulatory agency.

All records related to the management of individual conflicts of interest in research will be maintained in the HRPP office for at least 3 years following the completion of the research.

F. **Noncompliance with RCOIC recommendations**

Management plans will be monitored by the IRB office every six months. The status of current plans will be reported to the IRB and reflected in the minutes. Instances of noncompliance with recommendations or procedures for managing conflicts of interest will be managed as outlined in the Procedures for Human Research Protections, IV.X *Responding to Non-Compliance with Human Research Protection Requirements.*

G. **Public Accessibility**

The HRPP Coordinator will make information available concerning identified SFCOIs held by a covered individual to any requestor within 5 business days of the request. This information will include the covered individual's name, title and role with respect to research, the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

H. **Training**

Each investigator, research staff member, and IRB member will complete training regarding the SFCOI regulations and UPHDM policy prior to engaging in research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements.
- An investigator is new to the Institution
- The Institution finds an Investigator, research staff member, or IRB member noncompliant with Institution's FCOI policy or management plan.

The required training will consist of a review of current UPHDM policy: “Policy and Procedures for Managing Individual Financial Conflicts of Interest in Research.” Following review, the covered individual will acknowledge review and understanding of the policy and their responsibilities by signing an acknowledgement statement. The statement will be kept on file in the HRPP office and updated every 4 years or as circumstance require as outlined in this section. UPHDM may accept the training done by outside research groups if the training complies with the requirements set forth in federal regulation and UPHDM policy and procedure.

l. **Review of policy and procedures**
The RCOIC will review its policy and procedures every two years or more frequently if necessary.