UnityPoint Health
Des Moines

TITLE: **INSTITUTIONAL CONFLICTS OF INTEREST DISCLOSURE:** Policy: **UPHDM002**

I. PURPOSE

This policy establishes principles and procedures designed to ensure that research involving human subjects at UnityPoint Health - Des Moines (UPHDM) is conducted free from any untoward influence stemming from UPHDM's financial interests or commitments.

II. POLICY

UPHDM will establish and maintain an oversight process to manage, reduce or eliminate institutional conflicts of interest.

III. DEFINITIONS

A. Conflict of Interest (COI)
A potential or actual COI exists when commitments and obligations to UPHDM, or to widely recognized professional norms, or to the integrity or independence of medical or scientific decisions are likely to be compromised, or perceived to be compromised, by a person's outside interests or commitments, especially financial interests.

B. Investigators
- Principal investigator (PI): Person who is responsible for the design, conduct, and reporting of research.
- Co-Investigator (Co-I): Person who participates in the design, conduct, and reporting of research.

C. Members of the Immediate Family
Spouse, dependents, and all members of the disclosing person's immediate family including spouse, birth or adoptive parent, child, siblings, step-relations, father/mother/sister/brother –in-law, or grandparents.

D. Research Involving Human Subjects
For purposes of this policy, human subject research will mean any research which requires the review of UPHDM Institutional Review Boards (IRBs).

E. Research Conflict of Interest Committee (RCOIC)
RCOIC will consist of the Regional Hospital Compliance Officer or their designee; the Director of Ethics; the IRB Chair or Vice-Chair; and the Human Research Protection Program Manager.

F. Significant Financial Interest (SFI)
An SFI is an interest in which the individual or organization directly or indirectly (through business, investment, or family):
1. maintains an actual or potential ownership or other investment in the industry entity funding and/or associated with Research;
2. maintains an actual or potential compensation arrangement with the industry entity funding and/or associated with a research study, including direct and indirect remuneration as well as

any gifts; or

3. serves on the board of directors or has some fiduciary or official relationship with an organization that has significant commercial transactions with an industry entity associated with a research study.

IV. PROCEDURES

A. The Human Research Protection Program (HRPP) office will request an Institutional Interest report from the CFO, or their designee, annually.

B. RCOIC process for Review of Disclosure Statements:

1. After submission of the written disclosure statement, the RCOIC will review submitted materials to determine whether any COI exists.

2. The RCOIC will request supplementary information from any research team member or the IRB, Chief Compliance Officer, or Executive Director of Compliance as needed for their review.

3. If after review the RCOIC concludes that a COI exists, the RCOIC must then determine if the conflict can be managed according to guidelines.

4. If after review the RCOIC concludes that there are not conflicts, the Investigator may submit the research protocol to the UPHDM IRB.

C. Conflict of Interest Management:

1. If an identified COI is concluded to be manageable by the RCOIC, the management plan (e.g., disclosure, management, elimination) shall be developed in order to protect the study's validity, will be put in writing and then submitted to the appropriate UPHDM IRB for approval.

2. At a minimum, such management plans will include disclosure(s) of the interest to the research subjects.

3. The RCOIC will notify the PI in writing that a disclosed Interest was reviewed and deemed manageable or not manageable, and further that the research team members must abide by the management plans set forth in writing. The PI will respond in writing to the RCOIC. This will be communicated to the IRB and the Chief Compliance Officer or Executive Director of Compliance before the study is submitted to the UPHDM IRB.

4. If a COI arises and the RCOIC concludes management is not possible, the Research Study will not be eligible for UPHDM IRB review.

5. The final determination of COI existence and management plan rests with the IRB.