Human Research Protection Program Procedures

IV. Basic Procedures for Human Research Protections

AA. Conflict of Interest Disclosure

All members of the IRB, all investigators, all research study staff, and each consultant used for review of research must complete a “Conflict of Interest Disclosure” form describing any significant financial interest in research. This form is to be submitted to the IRB Office annually, and updated as changing circumstances may warrant, and be readdressed with each new protocol submission by the investigator. Annual disclosures will be evaluated by the Research Conflict of Interest Committee (RCOIC). When appropriate, the RCOIC will suggest ways to manage conflicts. At least one member of the RCOIC will be a voting member of the IRB. The convened IRB is informed of the RCOIC’s determination and proposed management plan. The IRB has the final authority to determine whether or not there is any interest that requires managing. Once the management plan is approved by the full board, a letter explaining the management plan is sent to the investigator/study team member. COI forms from other institutions may be submitted for IRB review. The RCOIC Committee makes the final determination if the form will be accepted in lieu of the UnityPoint Health Des Moines COI form.

The following are definitions of different types of potential conflict to interests:

1. A **conflict of interest** may exist when an individual has an interest that may compromise or have the appearance of compromising the professional judgment of the individual. For example, a conflict of interest could affect the oversight of research, choice of research protocols, the enrollment of human subjects, the collection and interpretation of data, or the reporting of results. A conflict of interest may result from interests that are either financial or associational in nature (collectively, an “Interest”).

2. A **financial interest** is an interest that stems from an individual’s or entity’s financial relationship with another individual or entity. A financial interest may arise from a compensation arrangement or an ownership arrangement.
3. An associational interest is an interest that stems from a covered individual’s or entity’s formal or informal participation in or involvement with (directly or indirectly such as through a family member) an organization or entity that, in turn, has a financial or economic stake in an industry entity engaged in research activities. A covered individual means 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. Neither the IRB reviewer nor their immediate family may have financial interests related to the research. Immediate family means 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.

Conflicts may be most likely to occur or appear to occur in regard to Interests in relation to financially interested persons or entities. A financially interested person or entity is a person or entity which would reasonably appear to affect or be affected by the conduct or outcome of a research project at a UnityPoint Health Des Moines facility. This term includes: (1) the manufacturer or distributor (including business partners and affiliates) of any drug, device or other process being used in the research; (2) any entity acting as the agent of the sponsor of the clinical research or other company with an Interest (e.g. a contracted research organization); and (3) a company that provides direct or primary competition for the investigational product if the investigator actually knows the financial interests of the company would reasonably appear to affect or be affected by the research (each a “Financially Interested Entity”).