

UnityPoint Health Des Moines
July 2025-June 2026
CONFLICT OF INTEREST EDUCATION AND DISCLOSURE FORM

Please read the following education before completing your disclosure form. This information will be helpful in completing the following form completely and accurately. Your completion of the form will serve as acknowledgment of education completion.

DEFINITIONS:

- **Conflict of interest** (COI) 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").
- **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.
- 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.
- **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.
- 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.
- 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").

To ensure that reporting requirements for funding or regulatory agencies are met, all members of the IRB, all investigators, all research study staff, and each consultant used for review of research (covered entities) must review the educational material attached to the "Conflict of Interest Disclosure" form and complete the 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. Conflict of interest education is required at least every 4 years through CITI. Additional education will be required if a researcher or other covered entity is non-compliant with the UPHDM IRB Conflict of Interest Policy and Procedures.

A completed and signed COI form will indicate review and understanding of the attached educational material.

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 there is any interest that requires managing. Management of a potential conflict of interest might include, but is not limited to:

- While study activity takes place, suspension of educational or consulting services that are provided by the investigator and paid for by the sponsor of the research.
- While study activity takes place, funds incurred by the covered individual from the study sponsor for services rendered may be required to be donated to a foundation or contributed to the general operating fund of the covered entities business or practice.
- Recusal from voting by an IRB member that has financial or other interest in a study reviewed by the IRB.
- When a financial interest is disclosed but no current conflict exists, the party will be asked to report any future involvement with the particular entity.

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.

Please complete the form and return to:

UnityPoint Health-Des Moines IRB Office
Iowa Methodist Medical Center
1200 Pleasant Street
ERC Building, Ground Floor, Health Sciences Library
Des Moines, IA 50309
E-Mail: irbsubmissions@unitypoint.org

Please include a written description of any disclosed information on a separate sheet of paper.

UnityPoint Health Des Moines

July 2025-June 2026

(Effective July 1, 2025 – June 30, 2026)

CONFLICT OF INTEREST DISCLOSURE FORM

This form must be completed **annually** (at minimum) by anyone who is involved in a research endeavor at a UnityPoint Health Des Moines facility, including investigators and all research staff and all who oversee the research, including Institutional Review Board members. **It is the responsibility of the individual completing this disclosure to update this information with the IRB whenever the circumstances change.**

Please submit this form to the Institutional Review Board Office: IMMC, 1200 Pleasant Street, ERC Building - Health Sciences Library, Des Moines, IA 50309 • irbsubmissions@unitypoint.org

To help us better identify potential or actual conflicts of interest, please complete the table by making a mark in the appropriate column. For any "Yes" answers, please provide a detailed explanation of the disclosure on a separate sheet of paper and return to the IRB.	Yes	No
<p>1) Do you, or any member of your immediate family, or any entity controlled or directed, directly or indirectly, by you, receive any <i>compensation</i> from a Financially Interested Entity?</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none">(i) Consulting fees(ii) Honoraria (including from a third party, if original source is a Financially Interested Entity)(iii) Gifts or other emoluments(iv) "In kind" compensation from a Financially Interested Entity (or entitlement to the same), whether for consulting, travel, lecturing, service on an advisory board, or for any other purpose not directly related to the reasonable cost of conducting research (as specified in the research agreement)(v) Training, teaching, or lecturing for a company or entity for which you are compensated that you also are currently acting as principle investigator or sub-investigator for that same company or entity <ul style="list-style-type: none">• If yes, please attach a separate sheet of paper with the following information:<ul style="list-style-type: none">- what is the aggregate amount of this compensation in the last 12 months?- what is the aggregate amount you expect to receive in the next 12 months?	<input type="checkbox"/>	<input type="checkbox"/>
<p>2) Do you participate in PHS funded research?</p> <p>If yes, please provide a disclosure of travel related expenses paid:</p> <ul style="list-style-type: none">(i) Purpose of the trip: _____(ii) Sponsor or organizer: _____(iii) Destination: _____(iv) Duration: _____	<input type="checkbox"/>	<input type="checkbox"/>
<p>3) Do you, or any member of your immediate family or any entity controlled or directed by you, or any member of your immediate family have any <i>ownership interest</i> in any of the following?</p> <ul style="list-style-type: none">(a) Equity interests, including stock options, of any amount in a non-publicly traded Financially Interested Entity(b) Equity interests in a publicly traded Financially Interested Entity that exceed \$5,000 in the aggregate for the entire family(c) Royalty income or have the right to receive future royalties under a patent license or copyright, or other intellectual property interest(d) Non-royalty payments or entitlements in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution.) This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred,	<input type="checkbox"/>	<input type="checkbox"/>

whether such payments are received from a Financially Interested Entity or from the institution on milestone payments tied to the achievement of research results. (e) Other ownership interest not addressed above		
4) Do you, or any member of your immediate family or any entity controlled or directed by you or any member of your immediate family serve as an officer, director, employee, independent contractor, advisor, agent, or in any other fiduciary role for a Financially Interested Entity, regardless of whether remuneration is received for such service?	<input type="checkbox"/>	<input type="checkbox"/>
5) Is there any financial relationship between your employer, group practice, or practice entity and any Financially Interested Entity that will exceed \$5,000/calendar year?	<input type="checkbox"/>	<input type="checkbox"/>
6) No list of examples of Interests that might cause or appear to cause a conflict of interest can be complete. Do you have reason to believe that you may have an Interest that the Institutional Review Board should be aware of prior to its work that is not covered by your answers above?	<input type="checkbox"/>	<input type="checkbox"/>
7) I am completing this form because I am: (select all that apply) <ul style="list-style-type: none"> <input type="checkbox"/> An Investigator/study team member listed on an active study <ul style="list-style-type: none"> • I have read the UnityPoint Health Des Moines IRB Investigator Handbook and understand my duties as a research investigator and study team member. <input type="checkbox"/> An IRB Board Member <input type="checkbox"/> A HRPP staff member 		
<input type="checkbox"/> I hereby certify that the information set forth above is true and complete to the best of my knowledge. In addition, I certify that I will make further disclosures as my personal interests change. I have reviewed, and agree to abide by, the UnityPoint Health Des Moines Conflict of Interest Policy, and the HRPP/IRB Conflict of Interest Procedures.		
Name <u>with</u> Credentials (print):		
Email Address:		
Signature:		Date:

Revised: April 2025