

UnityPoint Health Des Moines
July 2020-June 2021
CONFLICT OF INTEREST DEFINITIONS

Please read the following definitions and explanations carefully. This information will be helpful in completing the following form completely and accurately.

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").

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.

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 regarding 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").

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 2020-June 2021
(Effective July 1, 2020 – June 30, 2021)
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 • Fax: 515-241-3383 •
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
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? <i>Examples include:</i> (i) Consulting fees (ii) Honoraria (including from a third party, if the 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, lecturing, travel, 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 (a) If yes, what is the aggregate amount of this compensation in the last 12 months? _____ (b) If yes, what is the aggregate amount you expect to receive in the next 12 months? _____		
2) 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? (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, 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 _____		
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 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?		
4) 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?		
5) 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?		

Name <u>with</u> Credentials (print):	E-Mail Address:
Signature:	Date:
(IRB Office Use Only):	



Where to Go for Care During COVID-19

In our effort to reduce community spread of COVID-19, we are asking all patients to PLEASE CALL AHEAD before visiting a clinic. Click Learn More to find out how to make an informed choice about where to go for care during the COVID-19 pandemic.

[Learn More](#)

[Continue](#)

For

PRIOR

REVI

Form

using

change in federal regulations.

New Study Applications - Local IRB Review

All new local studies must accompany the IRB Application for New Protocol, an informed consent OR a Request for Waiver of Informed Consent, Study protocol, COI forms and human subjects training certificates for every person listed on the study application. IRB staff will not process the materials for final review until all items are received and complete.

Application to Conduct Research Involving Human Subjects (1/2019)

Application to Conduct Research: Chart Review of Human Subjects (6/2019)

Informed Consent Template (1/2019) - in compliance with the new Common Rule federal regulations (1/2019)

Child Assent (1/2019) - to be used when study subjects include children between 12-17 years old

Patient Participation Statement (12/2018) - can also be used when study subjects include children between 12-17 years old

Application to Review PHI in Preparation of Research (5/2018)

Request for Waiver/Documentation of Informed Consent (5/2018)

Example of Simple Protocol (5/2018) - to be used for non drug/device studies

UPHDM IRB Financial Conflict of Interest Form(2019-2020)

CITI Human Subjects Training (See Education Tab for More Information)



Urgent Care - Altoona



Where to Go for Care During COVID-19

In our effort to reduce community spread of COVID-19, we are asking all patients to PLEASE CALL AHEAD before visiting a clinic. Click Learn More to find out how to make an informed choice about where to go for care during the COVID-19 pandemic.

[Learn More](#)[Continue](#)[Reserve Your Spot >](#)[Click To Call >](#)

Examples of an external Central IRB would be NCI-CIRB, Western IRB, Quorum, etc. Whenever a study will utilize hospital departments, such as lab, radiology, etc., you must follow the Central IRB Notification Process outlined in the HRPP Procedures (Sections O & P)

For additional information regarding CIRB studies, please refer to the HRPP Procedures, Sections O & P.

Revisions/Amendments to Previously Approved Studies

Use this form when you have to make a change to a previously approved protocol. Please submit a separate sheet of paper to explain the changes you wish to make to the study.

Request for Revision/Amendment (6/2019)

Continuing Review/Administrative Updates

For all studies approved 1/20/19 or prior, **Continuing Reviews** are required to be conducted annually.



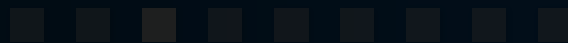
Location Wait Times

Urgent Care - Altoona



Where to Go for Care During COVID-19

In our effort to reduce community spread of COVID-19, we are asking all patients to PLEASE CALL AHEAD before visiting a clinic. Click Learn More to find out how to make an informed choice about where to go for care during the COVID-19 pandemic.

[Learn More](#)[Continue](#)[Reserve Your Spot >](#)[Click To Call >](#)

Non-Compliance Report Form (5/2018) - This form is to be used for internal events that are unforeseen, related to the research and indicate that participants or others are at increased risk of harm. This form is to be used for serious adverse events, unanticipated problems and protocol deviations and violations.

Internal events are events that occur within our institution.

External events are events that occur at another institution where the study is occurring. External events do not need to be reported to the local IRB.

A protocol violation is an accidental or unintentional change to the IRB approved protocol, that harmed participants or others that indicate participants or others **may be at increased risk or harm**.

A protocol deviation is an abnormality with a particular study that occurs with such frequency that this **may have an adverse effect** on the risk/benefit analysis of the study.

[Requests for Exemption From IRB Review Form](#) (per 2018 regulations)

[UPHDM IRB Exemption Categories Tool](#) (1/2019)



Location Wait Times

Urgent Care - Altoona



Where to Go for Care During COVID-19

In our effort to reduce community spread of COVID-19, we are asking all patients to PLEASE CALL AHEAD before visiting a clinic. Click Learn More to find out how to make an informed choice about where to go for care during the COVID-19 pandemic.

Learn More

Continue

Reserve Your Spot >

Click To Call >



CONTACT US

About Us

General Information: (515) 241-6212

Media Inquiries: (515) 205-6090

MyUnityPoint

AREAS OF EXCELLENCE

Behavioral Health

Pediatrics

Maternity Services

Radiation Oncology

Orthopedics

Primary Care

Emergency Care

more than anything else.

You are not a diagnosis, our ten o'clock appointment, or a label on a bill. Just a wonderfully important person with a name, with a need and with feelings.

Know how much *You Matter* to this world.



Where to Go for Care During COVID-19

In our effort to reduce community spread of COVID-19, we are asking all patients to PLEASE CALL AHEAD before visiting a clinic. Click Learn More to find out how to make an informed choice about where to go for care during the COVID-19 pandemic.

Learn More

Continue

Reserve Your Spot >

Click To Call >

