UnityPoint Health
Des Moines

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IRB Investigator Handbook

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1. PURPOSE

This handbook describes the responsibilities of investigators conducting Human Subject Research overseen by the UnityPoint Health Des Moines Institutional Review Board (IRB). The IRB is a group of people established to protect the rights and welfare of human research subjects. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy.

For research overseen solely by an IRB other than the UnityPoint Health Des Moines IRB, investigators should follow the requirements of that IRB.

2. INVESTIGATOR RESPONSIBILITIES

a) If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study. The IRB Office can be reached by phone at 515-263-5551 or by email at irbsubmissions@unitypoint.org.

b) Do not begin research until you have the IRB approval letter and obtained all other required approvals, such as radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources.

c) Comply with all requirements and determinations of the IRB. The IRB Procedures can be found online at www.unitypoint.org/irb.

d) Ensure that there are adequate resources to safely carry out the research. This includes, but is not limited to, sufficient investigator time, appropriate research team members, access to potential subjects, equipment and space.

e) Ensure that all research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and,

when relevant, privileges) to perform procedures and duties assigned to them during the study.

1. Investigators and research staff are required to complete or provide evidences of a completed human subjects training within the past 5 years and recomplete training if it expires during the course of the research. The IRB accepts NIH or CITI human subject's trainings. The IRB requires the completion certificate to be submitted to the IRB with study application materials.

2. Annually, investigators and research staff must read the current annual IRB Conflict of Interest procedure and complete the current IRB Conflict of Interest form prior to conducting any study related activity.

f) Personally conduct or supervise the research.

g) Conduct the research in accordance with the relevant current protocol approved by the IRB.

h) Protect the rights, safety, welfare, confidentiality and privacy of subjects involved in the research.

i) Submit proposed study protocol and consent modifications to the IRB prior to their implementation via the IRB form, Request for Revision/Amendment of an Approved Protocol. Current forms are available online at www.unitypoint.org/irb. Please make sure to check the website often to ensure you are using the most current IRB forms.

1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

j) Submit continuing reviews when requested by the IRB. If the continuing review documents are not received by the deadline established by the IRB Office, the study will go through an administrative closure and all study related activity must cease. The Principal Investigator will then be required to submit documents for a new study submission once a study is closed.

k) Submit a final study closure form to close the research study when all of the following have occurred:

- The protocol is permanently closed to enrollment
- All local subjects have completed all protocol related interventions and interactions
- For research subject to federal oversight other than FDA:
  - No additional identifiable private information about the subjects is being obtained
  - Your analysis of private identifiable information is completed

l) If research approval expires, stop all research activities and immediately contact the IRB.

m) Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.").

n) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.

o) Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:

- Adults unable to consent
- Children
- Neonates of uncertain viability
- Nonviable neonates
- Pregnant women
- Prisoners
- Individuals unable to speak English

p) When consent, permission, or assent is required by the IRB, ensure that they are obtained and documented in accordance with the current protocol as approved by the IRB.

q) Follow the IRB's requirements to disclose financial interests:

- Disclose your financial interests should have occurred prior to submission of an initial review. Report to the IRB changes to your financial interests within 30 days of discovery or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest that would have required disclosure on initial review.

r) The IRB retains study related records for three years after the study has gone through final closure. The PI should retain records as set forth in the study sponsor agreement, when applicable.

s) Employ sound study design in accordance with the standards of your discipline and design studies in a manner that minimizes risks to subjects.

t) Update the IRB with any changes to study personnel and wait for their formal approval before allowing them to engage in research activities.

u) If you are the lead investigator of a multi-site study, ensure there is a plan to manage information that is relevant to the protection of subjects, such as Unanticipated Problems Involving Risks to Subjects or Others, interim results, and protocol modifications, and submit that plan to the IRB with your protocol.

v) Promptly report to the IRB the information listed in Section G of the IRB Procedures. All event forms can be found online on the IRB website www.unitypoint.org/irb.

REGULATORY RESOURCES

FDA Regulations

CFR - Code of Federal Regulations Title 21, Part 50
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

CFR - Code of Federal Regulations Title 21, Part 56
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

U.S. Department of Health & Human Services

HHS – Human Subject Research Title 45, Part 46
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

CONTACT US

Please address all questions and concerns to the IRB Office at irbsubmissions@unitypoint.org.