UnityPoint Health
Des Moines

Institutional Review Board
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IRB Investigator Handbook

Effective: 9/21/15
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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 515-241-8598 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 Human-research-protection-program-procedures.

d) Each researcher is accountable and responsible for actions initiated under their electronic signature for all IRB documents. For IRBManager, each user is accountable and responsible for maintaining confidentiality of their username and password and must not disclose their username and password to anyone else.

e) 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.

f) 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 evidence of a completed human subjects training within the past 3 years and repeat training if it expires during the research. The IRB will only accept CITI human subjects training. However, the IRB will accept Good Clinical Practice (GCP) training certifications in lieu of CITI training. The CITI completion certificates do not need to be submitted to the IRB if the modules were completed under the UnityPoint Health Institution affiliation link. By affiliating yourself with UnityPoint Health Des Moines when creating a login to the CITI site, the modules can be taken free of charge.

2. Investigators and research staff are also required to have completed CITI Conflict of Interest training within the past 4 years and repeat training if it expires during the research. The IRB will accept CITI Conflict of Interest training that was completed through another institution after review of the modules completed satisfies the necessary requirements of the UnityPoint Health Des Moines IRB. The CITI completion certificates do not need to be submitted to the IRB if the modules were completed under the UnityPoint Health Institution affiliation link. By affiliating yourself with UnityPoint Health Des Moines when creating a login to the CITI site, the modules can be taken free of charge.

3. 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. Conflict of Interest forms are sent out in July of each year.

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.

1. Submit proposed study protocol and consent modifications to the IRB prior to their implementation via the amendment xform in IRBManager (https://up.my.irbmanager.com) . Do not make modifications to the research

without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

i) Submit continuing reviews and administrative updates when requested by the IRB. Please note that reminder emails come directly from IRBManager and include links to forms you will need for your continuing review or administrative update. 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.

j) Submit a final study closure xform within IRBManager to close the research study when all 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

k) If research approval expires for any reason, stop all research activities and immediately contact the IRB.

l) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”).

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

n) 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

o) 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.

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

- Disclosure of 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.

q) 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.

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

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

t) 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 Issues of Non-Compliance, interim results, protocol modifications and submit that plan to the IRB with your protocol.

u) Promptly report to the IRB the information listed in Section G of the IRB Procedures. The Issues of Non-Compliance form and the 24-hour SAE form can be found on IRBManager.

3. INVESITGATOR RESPONSIBLITIES WHEN CONSIDERING ENROLLING SUBJECTS WITH DIMINISHED CAPACITY

The researcher will provide the IRB information to evaluate the consent process including:

- Any waiting period between informing the prospective participant and obtaining consent.
- Steps taken to minimize the possibility of coercion or undue influence.
- The researcher will give the prospective participant or legally authorized representative sufficient opportunity to consider whether to participate in the research.

When following DHHS regulations:

- To allow use of the long form of consent documentation, the IRB determines the researcher will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

When following the FDA regulations:

- Include a statement that the results of the research will be posted on clinicaltrials.gov, "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."
- The researcher will give either the participant or the legally authorized representative adequate opportunity to read the consent document before it is signed.

REGULATORY RESOURCES

FDA Regulations

CFR - Code of Federal Regulations Title 21, Part 50
eCFR :: 21 CFR Part 50 -- Protection of Human Subjects

CFR - Code of Federal Regulations Title 21, Part 56
eCFR :: 21 CFR Part 56 -- Institutional Review Boards

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** or by calling 515-241-8598.