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 515-241-8598 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 (section 4 below) 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.

4. UPHDM Policy and Procedures for Managing Conflicts of Interest in Research:
   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. 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:

a) 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.
b) 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.
c) Recusal from voting by an IRB member that has financial or other interest in a study reviewed by the IRB.
d) 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.

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

a) 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 subject, 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").

b) 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.

c) 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").

g) Personally conduct or supervise the research.

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

i) Adhere to the General Requirements for Informed Consent per the Human Research Protection Program Procedure Manual as outlined below:

1) <u>General Requirements for Informed Consent (45CFR46.116)</u>

General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (3) through (5) of this section. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (5) of this section. General waiver or alteration of informed consent is described in paragraph (6) of this section. Except as provided elsewhere in this policy:

(a) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(b) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative enough opportunity to discuss and consider whether to participate and that minimize the possibility of coercion or undue influence.

(c) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(d) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have to

make an informed decision about whether to participate, and an opportunity to discuss that information.

(e) Except for broad consent obtained in accordance with paragraph (d) of this section:

(1) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(2) Informed consent must present information in enough detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(f) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2) Basic elements of informed consent. Except as provided in paragraph (4), (5), or (6) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(b) A description of any reasonably foreseeable risks or discomforts to the subject;

(c) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(e) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; see IV. T "Certificate of Confidentiality" for additional procedures.

(f) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(g) An explanation of whom to contact for answers to pertinent questions about the research and research subject' rights, and whom to contact in the event of a research-related injury to the subject;

(h) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(i) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(1) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(2) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

3) <u>Additional elements of informed consent.</u>

Except as provided in paragraph (4), (5), or (6) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(a) A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(c) Any additional costs to the subject that may result from participation in the research;

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(e) A statement that significant new findings developed during the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(f) The approximate number of subjects involved in the study;

(g) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(h) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subject, and if so, under what conditions; and

(i) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

4) Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. UPHDM has chosen not to implement the use of broad consent currently.

5) <u>Waiver or alteration of consent in research</u> involving public benefit and service programs conducted by or subject to the approval of state or local officials:

(a) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (1) through (3) of this section, provided the IRB satisfies the requirements of paragraph (5)(c) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (4) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or

secondary research use of the identifiable private information or identifiable biospecimens.

(b) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (2) and (3) of this section provided the IRB satisfies the requirements of paragraph (5)(c) of this section. An IRB may not omit or alter any of the requirements described in paragraph (1) of this section.

(c) Requirements for waiver and alteration. For an IRB to waive or alter consent as described in this subsection, the IRB must find and document that the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(1) Public benefit or service programs;
(2) Procedures for obtaining benefits or services under those programs;
(3) Possible changes in or alternatives to those programs or procedures; or
(4) Possible changes in methods or levels of payment for benefits or services under those programs; and (ii) The research could not practicably be carried out without the waiver or alteration.
(5) The research is not regulated by the US FDA.

6) <u>General waiver or alteration of consent</u>

(a) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (1) through (3) of this section, provided the IRB satisfies the requirements of paragraph (6)(c) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (4) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(b) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (2) and (3) of this section provided the IRB satisfies the

requirements of paragraph (6)(c) of this section. An IRB may not omit or alter any of the requirements described in paragraph (1) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (4) of this section.

(c) Requirements for waiver and alteration. For an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(1) The research involves no more than minimal risk to the subject;

(2) The research could not practicably be carried out without the requested waiver or alteration

(3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(4) The waiver or alteration will not adversely affect the rights and welfare of the subject; and

(5) Whenever appropriate, the subject or legally authorized representatives will be provided with additional pertinent information after participation.

(6) The research is not regulated by the US FDA.

7) <u>Screening, recruiting, or determining eligibility</u>

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subject without the informed consent of the prospective subject or the subject's legally authorized representative, if the research is not regulated by the US FDA and either of the following conditions are met:

(a) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(b) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

8) <u>Posting of clinical trial consent form</u>

(a) For each clinical trial conducted or supported by a federal department or agency, one IRB approved informed consent form used to enroll subject must be

posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(b) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(c) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.

(d) The regulation allows for certain confidential information to be redacted at the time of posting. For example, certain confidential commercial information. Note that the regulation does not allow for exceptions to the requirement for posting, only permitted, or required redaction of certain confidential information by the agency.

(e) Preemption. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed for informed consent to be legally effective.

9) Emergency medical care. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). Adhere to the Documentation Requirements for Informed Consent per the Human Research Protection Program Procedure Manual as outlined below:

j) Documentation of Informed Consent

1) Requirement for written consent: Except as provided in paragraph (c) of this section, informed consent shall be documented using a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A template containing suggested language for a combined consent and authorization form can be downloaded from the IRB web page (www.unitypoint.org/irb). A copy of the fully executed document shall be given to the person signing the informed consent form.
2) Except as provided in paragraph (3) of this section, the consent form may be either of the following:

a. A written informed consent form that meets the requirements of 45CFR46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

b. A short form written informed consent form stating that the elements of informed consent required by 45CFR46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by 45CFR46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The short form includes required disclosures when the research involves private identifiable information or identifiable biospecimens. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

c. An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subject if it finds any of the following:
    i. That the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern, and the research is not regulated by the US FDA;
    ii. That the research presents no more than minimal risk of harm to subject and involves no procedures for which written consent is normally required outside of the research context and the research is not regulated by the US FDA; or
    iii. If the subject or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subject and provided there is an appropriate alternative mechanism for documenting that informed consent

was obtained. The oral or written information provided to the participants must include all required and appropriate additional elements of consent disclosure. Additionally, the research is not regulated by the US FDA.

k) Waiver of requirement for written consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subject if it finds either:

1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2) that the research presents no more than minimal risk of harm to subject and involves no procedures for which written consent is normally required outside of the research context.

3) 2018 Requirement

(a) If the subject or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subject and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(b) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subject or legally authorized representatives with a written statement regarding the research.

(c) FDA regulated research. If the research is subject to FDA regulation, only criterion (3) b. can be used in considering whether to waive the requirement.

(d) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subject with a written statement regarding the research. In cases in which the IRB requires a written statement regarding the research be given to the participant, the IRB must review this statement prior to approval of research.

The IRB reviewer utilizes the expedited or the exempt checklist to document their findings justifying the waiver or alteration.

(e) In cases where the research involves children and waiver of informed consent is considered:

(i) The IRB is allowed to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of parental permission are met.

(ii) The IRB is allowed to waive the requirement to document the parental permission by determining that the regulatory criteria for waivers are met.

l) Monitoring of the informed consent process:

The IRB may determine that the process of obtaining informed consent for a given protocol must be monitored. Such a situation may arise when the protocol proposes to enroll subject under unusual conditions or when concerns have been expressed about an investigator's approach to recruiting and obtaining informed consent from subject. The actions that the IRB may take in such a situation include, but are not limited to, requiring a third party, such as the Research Subject Advocate, to observe or participate in the consent process; interviewing subject after they have been recruited; and requiring the investigator to record the consent process.

m) Electronic Consent (eIC) in Human Subjects Research

1) Purpose

This procedure establishes the informed consent process and documentation that may be conducted utilizing an electronic platform and/or media in human subjects research.

eIC employs the use of electronic systems and processes, whether remotely or in-person, to convey information to a participant and/or document research consent. The electronic media can vary depending on the type of system utilized and can include the use of applications, videos, graphics, interactive text, etc.

eIC may be used in several different methods and time-points during the eIC process. For example:

a) This process can take place at the research study site where both the investigator (or other authorized member of the research team) and the subject/legally authorized representative are at the same location ("In-Person e-IC");

b) Remotely where the subject reviews the consent information in the absence of the investigator/research team member ("Remote e-IC").

2) IRB must approve the eIC process and forms used during the informed consent process prior to implementation in the study. The methods to be utilized in the eIC process must be submitted to IRB in a format that facilitates this review and includes a sufficient description of the eIC process and the platforms, systems, and/or media employed. EIC employs the use of electronic systems and processes, whether remotely or in- person, to convey information to a participant and/or document research consent. The electronic media can vary depending on the type of system utilized and can include the use of applications, videos, graphics, interactive text, etc.

Any subsequent changes to the eIC process also requires IRB approval prior to implementation, unless the proposed alteration is required to eliminate an immediate hazard to participants or staff.

If requested, or required, the subject/legally authorized representative must have the option to use paper-based forms completely or partially.

The subject/legally authorized representative must be provided a copy of the fully executed, signed informed consent/assent form either in hard copy or as an electronic file that can be stored on their own personal device of choice.

3) Requirements During eIC and Guiding Principles
   It is not the intention of the IRB to limit eIC use to specific electronic platforms or methods.

   The eIC platform/application must comply with the regulations outlined in 21CFR Part 11. For FDA regulated studies, it is the researcher' responsibility to provide documentation to the IRB that the proposed eIC complies with all applicable requirements under 21 CFR Part 11.

   The principles that govern in-person informed consent still apply during an eIC process. Refer to procedures in IV.S. of the IRB Procedures.

   An eIC process may also be utilized when the IRB has waived the requirement to obtain a signature on a consent form. With this waiver, the eIC process still includes an information sheet that is provided to the subject/legally authorized representative in its entirety. A checkbox response that states “I agree to participate” should be used to verify/confirm consent prior to initiating study procedures.

4) eIC and Privacy
   Privacy measures require extra consideration during a remote eIC process. If during the eIC process the person obtaining consent is remotely located (i.e., the consent process is conducted via a call, video conferencing, or other e-messaging method) the subject should be reminded to find a private location to help ensure privacy of this discussion.

   The system that supports e-IC must be secure, utilize restricted access (e.g., unique users and password protection) and store records of the subject’s

identity, study participation and personal information, so that subject confidentiality is protected.
Special attention is needed when vulnerable or special populations are included and there should be an adequate plan in place to obtain eIC for the needs of these populations.

5) Electronic Signature
Ensures compliance with the definition of electronic signature as defined in Section IV(d).

The platform for the eIC is to include a method to ensure that the person electronically signing the informed consent document, or providing their consent, is the subject who will be participating in the research study or is the subject's legally authorized representative.

For studies in which HIPAA Authorization is required, this may be obtained utilizing an eIC platform to obtain an electronic signature. The HIPAA regulations also include that the subject/legally authorized representative's typed name is equivalent to an electronic signature.

6) eIC and Vulnerable Populations
   a) Non-English speaking subjects:
   Investigators are to incorporate an interpreter into the eIC process. Refer to procedures in VIII.B. of the IRB Procedures.

   Special attention is required when there is a need for a short form in an eIC process. This may apply when the eIC process is conducted "in-person" or "remotely". At the time of consent, the investigator or designated study team member, are to be aware of this need for the addition of a translated short form to the eIC process/platform and include an interpreter for the non-English speaking subject.

   b) Legally Authorized Representatives (LAR) for Adults:
   If a legally authorized representative is to provide consent for an adult subject, the principles for obtaining informed consent via the eIC platform still apply. Refer to procedures in VIII.B. of the IRB Procedures.

   When possible, the eIC application/process should accommodate the special needs for adults that are visually or hearing impaired, or illiterate.

The IRB may also make determinations that assent from the adult subject is needed. In these cases, this adult assent process is also to be incorporated into the eIC process.

The IRB may also make determinations that assent from the adult subject is needed. In these cases, this adult assent process is also to be incorporated into the eIC process.

c) Children:
When children are to be enrolled, the investigator will need to incorporate the IRB approved assent process in the eIC procedures/platform. If needed, assent can be obtained in the same way the parental permission was obtained. Refer to procedures in IX.C. of the IRB Procedures.

n) 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.

o) 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.

p) 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
- The research is prematurely completed
- 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

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

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

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

t) 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

u) 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.

v) 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.

w) 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.

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

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

z) 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.

aa) 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.