

INSTITUTIONAL REVIEW BOARD
SOP 412: Informed Consent for Research

POLICY

The consent form shall comply with the requirements of federal regulations found in 21 CFR Part 50, 45 CFR 46.116, and meet the requirements set forth by the DMH IRB. No investigator may involve a human being as a research subject without first obtaining the legally effective informed consent of the subject or the subject's legally authorized representative.

PROCEDURES

1. General Requirements

- 1.1 An Investigator or clinical research coordinator will seek informed consent only under circumstances that provide the prospective subject or the subject's legally authorized representative sufficient opportunity to consider whether or not to participate.
 - 1.1.1 Subjects may certify that they understand the statements in the consent form and are satisfied with the explanation provided during the consent process (e.g. "I understand the statements in the consent form.") Subjects should not be required to certify completeness of disclosure (e.g. "This study has been fully explained to me," or, "I fully understand the study.")
 - 1.1.2 There shall be no unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects.
 - 1.1.3 If subjects are paid for participation, the schedule of all payments should be presented to the IRB at the time of initial review and outlined in the consent form. Payment should accrue as the study progresses and should not be contingent upon completion of the entire study. Payment of a small portion for completion of the study is acceptable provided that such incentive is not coercive.
- 1.2 The information that is given to the subject or the subject's legally authorized representative must be in a language understandable to the subject or the subject's legally authorized representative.
 - 1.2.1 Technical and scientific terms must be adequately explained or replaced with common terms.
 - 1.2.2 If it is anticipated that the subject population will routinely include non-English speaking subjects or the consent interviews will be conducted in a language other than English, a translated consent form is required and should be submitted at the time of initial review or prior to any subject consenting.
 - 1.2.3 Oral translation may be utilized if a non-English speaking subject is unexpectedly encountered. A "short-form" written consent document in a language the subject understands must be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally.
- 1.3 The consent process and the research procedures may be observed by an IRB voting member, the IRB administrator, the Manager of Clinical Research, or a third party appointed by an IRB Co-Chair. See: Informed Consent Monitoring Policy
- 1.4 A signed copy of the consent form shall be given to the subject or the subject's legally authorized representative.

2. Basic Elements of Informed Consent

- 2.1 The IRB has developed standard language and format to be used in portions of all consent forms. The proposed consent form must follow the DMH approved consent template and must contain all of the following requirements:

- 2.1.1 A statement that the study involves research, an explanation of the purpose(s) of the research, how many people will take part in the study, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - 2.1.1.1 Any procedures relating solely to research (e.g. randomization, placebo control, additional tests) should be explained to the subjects.
 - 2.1.1.2 Consent documents for studies of investigational articles should contain a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety. In studies that also evaluate the effectiveness of the test article, consent documents should include that purpose but not contain claims of effectiveness.
- 2.1.2 A description of any reasonably foreseeable risk or discomfort to the subject.
 - 2.1.2.1 Risks of procedures relating solely to research should be explained in the consent form. The tests required in the protocol which carry significant risk of morbidity/mortality should be explained and adverse effects not minimized.
- 2.1.3 A description of any benefit(s) to the subject or to others which may be reasonable expected from the research.
 - 2.1.3.1 Description of benefit(s) should be clear and not overstated.
 - 2.1.3.2 If no direct benefit(s) is (are) anticipated, that should be stated.
 - 2.1.3.3 If benefit(s) to "others" are different than those normally expected to result from conducting research and may be relevant to the subject's decision to participate, they should be disclosed in the consent form.
- 2.1.4 Disclosures of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - 2.1.4.1 Consent forms should briefly and sufficiently explain any pertinent alternatives to entering the study.
- 2.1.5 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and the possibility that the Food and Drug Administration may inspect the records.
 - 2.1.5.1 If any other entity, such as the sponsor of the study or drug manufacturer has access to the study records, the consent form must contain that information.
- 2.1.6 For research involving more than minimal risk, an explanation as to whether compensation and medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
- 2.1.7 An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
- 2.1.8 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3. Additional Elements of Informed Consent

- 3.1 When appropriate, one or more of the following elements of informed consent shall also be included in the consent form:
 - 3.1.1 A statement that a particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
 - 3.1.2 If measures to prevent pregnancy should be taken while in a study

3.1.3 The availability of counseling resources

3.2 Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.

3.2.1 An unexplained statement that the Investigator and/or sponsor may withdraw subjects at any time does not adequately inform the subject of anticipated circumstances for such withdrawal.

3.2.2 A statement that the investigator may withdraw a subject if he/she does not follow study procedures is not appropriate. A subject may be informed that he/she may be withdrawn if he/she does not follow the instruction given to them by the investigator.

3.3 Any additional costs to the subject that may result from participation in the research.

3.4 The consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject.

3.5 A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

3.6 The approximate number of subjects to be involved in the study.

4. Documentation of Informed Consent Process

4.1 Written

4.1.1 A written consent document that embodies the elements of informed consent as required by 45 CFR 46.116 or 21 CFR 50.25 must be presented. This form may be read to the subject or the subject's legally authorized representative, but in any event, the Investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

4.1.2 Signature requirements

4.1.2.1 Signature of the subject or the subject's legally authorized representative

4.1.2.2 Signature of the clinical research coordinator (CRC) or the Investigator

4.1.2.3 Signature of an impartial witness for illiterate English-speaking subjects, if applicable, and for subjects with impaired vision (blindness) if they do not have a legally authorized representative.

4.1.2.4 Only the subject or the subject's legally authorized representative should enter a date for the subject's or the legally authorized representative's signature. Any necessary corrections to the subject's date of signature should be made only by the subject or their legally authorized representative and not by the Investigator or the clinical research coordinator.

4.2 Oral

4.2.1 Informed consent information may be presented orally as indicated in 46.117(b)(2) when done in conjunction with a "short form" written consent document (stating that the elements of informed consent have been presented orally) and a written summary of what is presented orally. When this method is used with subjects who do not speak English:

4.2.1.1 The oral presentation and the "short form" written document must be in a language understandable to the subject;

4.2.1.2 The IRB-approved English language consent form may serve as the summary; and

4.2.1.3 The witness must be fluent in both English and the language of the subject, and may not be a member of the research team.

4.2.2 Signature requirements

4.2.2.1 The “short form” must be signed by the subject or the subject’s legally authorized representative

4.2.2.2 The summary must be signed by the clinical research coordinator (CRC) or the Investigator

4.2.2.3 The witness signs both documents.

4.3 Remote Consent

4.3.1 The written consent form may be sent to the subject or the subject’s legally authorized representative by email, by postal mail or by facsimile prior to (in advance of) the consent interview. It is a requirement that the subject or their legally authorized representative has a copy of the consent form to read and follow while the consent interview and discussion takes place. The person who conducts the consent interview needs to be knowledgeable about the study and be able to answer any questions.

4.3.1.1 If the consent form is delivered via postal mail, two copies must be mailed so that the subject or LAR is able to retain a copy for reference while their signed copy is in transit to the site and prior to receiving their final copy with all necessary signatures.

4.3.2 A witness must be present during the consent interview. The witness must be able to hear both sides of the conversation (e.g., speaker phone, Facetime, Zoom or other virtual interface).

4.3.3 Signature requirements

4.3.3.1 Signature of the subject or the subject’s legally authorized representative. If the potential participant or legally authorized representative agrees to participation, that individual signs and dates the consent form and returns it to the clinical research coordinator or the Investigator (e.g., via text, email, postal mail or facsimile). If postal mail is used, a pre-paid, self-addressed envelope should be provided to the subject or their legally authorized representative to mail the signed consent form back to the clinical research coordinator or the Investigator.

4.3.3.2 Signature of the individual (e.g., clinical research coordinator, Investigator) who conducted the consent interview. The consent form should be signed and dated by that individual upon receipt of the signed consent form from the subject or the subject’s legally authorized representative using the date it was received.

4.3.4 The method used for obtaining consent must be documented by the clinical research coordinator or Investigator on the signature page. It must specifically include the interface (e.g., speaker phone, FaceTime, Zoom) used for obtaining consent, the date of the consent interview, and the date the signed consent was received. For example, “Discussed with [subject or LAR name] via [name the interface used] on [insert date] and received signed consent form on [insert date].” Include a brief reason for performing the informed consent discussion over the speaker phone, FaceTime, Zoom, etc.

4.3.5 Documentation of the witness is also required. The name of the witness, their role or relationship to the subject, and the date of the consent interview must be recorded in the research records in order to document their participation.

4.3.6 The date the clinical research coordinator or the Investigator signs the consent form, not the date the consent interview took place, is the official date of informed consent for the subject on the trial.

5. Legally Authorized Representative (also refer to SOP 206: Special Populations - Decisionally Impaired)

5.1 The legally authorized representative (LAR) is the power of attorney (POA) or surrogate in the State of Illinois. The POA or surrogate should sign the consent form if the subject is incompetent/decisionally impaired.

5.1.1 For Illinois, the priority list for the legally authorized representative is as follows:

5.1.1.1 Court-appointed guardian, or proxy designed by durable power of attorney

5.1.1.2 Spouse or civil union partner

5.1.1.3 Any adult son or daughter

5.1.1.4 Either parent

5.1.1.5 Any adult brother or sister

5.1.1.6 Any adult grandchild

5.1.1.7 A close friend (requires affidavit); or

5.1.1.8 Guardian of the estate;

5.2 The legally authorized representative (LAR) in the State of Missouri is the legal guardian, attorney-in-fact, then family member. The LAR should sign the consent form if the subject is decisionally impaired.

5.2.1 For Missouri, the priority list for the legally authorized representative is as follows:

5.2.1.1 Legal guardian

5.2.1.2 Attorney-in-fact

5.2.1.3 Spouse

5.2.1.4 Adult child

5.2.1.5 Parent

5.3.1.6 Adult brother or sister; or

5.3.1.7 Relative by blood or marriage

6. Administrative Changes

6.1 Administrative changes are minor changes made to the consent form that may occur in two ways:

6.1.1 The regulatory compliance coordinator makes changes to the consent form at the time of continuing review and documents the changes in the submission form, or

6.1.2 The IRB administrator makes changes to the consent form post IRB approval.

6.2 Administrative changes may include, but are not limited to, one or more of the following:

6.2.1 Version date changes

6.2.2 Updates to contact information

6.2.3 Corrections of misspelled words

6.2.4 Bolding or unbolding of words or symbols

SCOPE

This SOP applies to all IRB members, the IRB administrator, and members of the research community.