PREFERRED CONSENT: INFORMED CONSENT FOR RESEARCH
STANDARD: GOOD CLINICAL PRACTICE
EFFECTIVE: 1/98; 11/03; 4/04; 2/06; 6/11; 10/14

POLICY:

The patient information and 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 subject in research without first obtaining the legally effective informed consent of the subject or the subject’s legally authorized representative.

Specific Policies

General Requirements

An investigator or clinical research associate 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. 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.”)

2. There shall be no unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects.

3. If subjects are paid for participation, the schedule of all payments must 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.

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. Technical and scientific terms must be adequately explained or replace with common terms.

2. If it is anticipated that the subject population will include non-English speaking people or the consent interviews will be conducted in a language other than English, a translated consent form is required and must be submitted at the initial review or prior to any subject consenting.

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 should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally.

4. If a prospective subject speaks and understands English, but does not read and write, the consent form may be read to them and informed consent may be documented by having the individual “make their mark” on the consent form (last section). There must be an impartial witness to attest to the adequacy of the consent process and to the subject’s voluntary willingness to participate.

The consent process and the research procedures may be observed by an IRB voting member, the IRB Administrator, the Director of Clinical Research, or a third party appointed by the IRB Chairperson.
**Documentation of Informed Consent**

The consent process shall be documented by the use of a written consent form approved by the IRB, and signed and dated by the subject or the subject’s legally authorized representative at the time of consent, and shall include one or more of the following signatures, as appropriate:

1. The Clinical Research Associate or the Investigator
2. A witness for illiterate English-speaking subjects, if applicable

In addition to signing the consent form, the subject or the subject’s legally authorized representative should enter the date of signature on the form to permit verification that consent was actually obtained before the subject began participation in the study.

A copy of the consent form will be given to the subject or the subject’s legally authorized representative.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 45 CFR 46.116 or 21 CFR 50.25. 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.

2. A short written document stating that the elements of informed consent required by 45 CFR 46.116 or 21 CFR 50.25 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and 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.

**Basic Elements of Informed Consent**

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:

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.
   a) Any procedures relating solely to research (e.g. randomization, placebo control, additional tests) should be explained to the subjects.
   b) 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. A description of any reasonably foreseeable risk or discomfort to the subject.
   a) Risks of procedures relating solely to research should be explained in the consent document. The tests required in the protocol which carry significant risk of morbidity/mortality should be explained and adverse effects not minimized.

3. A description of any benefit(s) to the subject or to others which may be reasonable expected from the research.
   a) Description of benefit(s) should be clear and not overstated.
   b) If no direct benefit(s) is (are) anticipated, that should be stated.
   c) 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.
4. Disclosures of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
   a) Consent documents should briefly and sufficiently explain any pertinent alternatives to entering the study.

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.
   a) If any other entity, such as the sponsor of the study or drug manufacturer has access to the study records, the informed consent document must contain that information.

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.

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.

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.

Additional Elements of Informed Consent
When appropriate, one or more of the following elements of information shall also be included in the consent form:

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.
   a) If measures to prevent pregnancy should be taken while in a study
   b) The availability of counseling resources

2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.
   a) 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.
   b) 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. Any additional costs to the subject that may result from participation in the research.

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

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.

6. The approximate number of subjects to be involved in the study.
Legally Authorized Representative

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. It is also reasonable to have the signature of the LAR if:
1. The subject has lost use of their hand and the ability to write
2. The subject has impaired vision

The priority list for the legally authorized representative is as follows:
1. Court-appointed guardian
2. Spouse
3. Adult child
4. Parent
5. Adult brother or sister
6. Adult grandchild
7. Close friend

Administrative Changes

Administrative changes are minor, insignificant changes made to the consent form that may occur in two ways:
1. The regulatory compliance coordinator makes changes to the consent form at the time of continuing review and outlines what changes have been made, or
2. The IRB administrator makes changes to the consent form post IRB approval.

Administrative changes may include, but are not limited to, one or more of the following:
1. Version date changes
2. Additions and deletions of investigators
3. Changes in addresses or telephone numbers
4. Corrections of misspellings
5. Italicizing words in parentheses
6. Bolding or unbolding words or symbols

APPLICABLE TO:
These policies and procedures apply to all research requiring prospective informed consent.

RESPONSIBILITY:
Regulatory compliance coordinators are responsible for updating the consent form at the time of continuing review as it relates to administrative changes.

IRB Administrator is responsible for making administrative changes in iMedRIS during the approval process.

APPROVED BY:

Executive Vice President