INSTITUTIONAL POLICY & PROCEDURE
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TITLE: Institutional Review Board Informed Consent
IC 702 Conducting the Informed Consent Process

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: This policy establishes the process to obtain informed consent from potential research participants, the legally authorized representatives of adults unable to consent, or the parents or guardians of children. The process begins when a study principal investigator or designated study team member identifies a patient or member of the community as a potential candidate for a research study. The process involves detailed discussion with the potential participant or the potential participant’s legally authorized representative and obtaining in writing legally effective informed consent specific to the research (agreement to participate) or recording of a declination to participate in the research. Informed consent is an on-going process and is particularly important for longitudinal studies. The PI should be available to answer participants questions at all times. Ongoing informed consent involves reminding participants of the purpose of the study, providing clarification of what is research and what is standard of care, reminding participants that they are still part of a research study and of the study procedures that will take place in the future. The process should involve ongoing information exchange and discussion throughout the entire time the participant is involved in the study.

GENERAL PROVISIONS:

The informed consent discussion is the process by which the research study is explained to the potential participant and the participant then voluntarily agrees to participate in the research. Informed consent to participate in a research study must be obtained from all participants (or their legally authorized representative) prior to their participation in the research unless the IRB has approved a waiver of informed consent.

Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, participant recruitment materials, verbal instructions, question/answer sessions and measures of participant understanding. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent discussion and process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the participant.

The IRB requires that the research team must obtain legally effective informed consent, prior to conducting any study-related procedure or intervention, from each research participant or from his/her legally authorized representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with federal regulations.

Definition of legally effective informed consent: All of the required elements of the informed consent are contained in the consent form document. The consent of the participant is obtained prior to conducting any study-related procedure or intervention, and the person signing the consent form is the participant or the participant’s legally authorized representative.
The clinical investigator is responsible for ensuring that informed consent is obtained from each research participant before that participant participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator may delegate a qualified study team member to conduct and obtain the informed consent of an individual. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research. If the investigator chooses to delegate an individual to the task of conducting the informed consent discussion the PI should select individuals with proper credentials, education and experience. The PI must ensure the individual has read and understands the protocol and informed consent document. The PI may want to be part of the first informed consent discussion in which they have designated a study team member to conduct to ensure the process takes place as they would expect and is required.

Each potential participant or legally authorized representative should be provided with a brief overview of the purpose of the study and the reason they are being asked to consider participation. Each potential research participant or legally authorized representative should be provided with a copy of the current Mercy Health IRB approved informed consent document in advance of the informed consent discussion. Potential participants and legally authorized representatives should have the opportunity to read the informed consent document and discuss the potential for study participation with their family or friends.

Once the potential participant or legally authorized representative has had time to review the informed consent document the principal investigator or study team member should ask the participant if they are interested in being part of the study. If the participant or legally authorized representative states they are interested, an in depth, effective and comprehensive conversation should occur covering all aspects of potential study participation. The full informed consent document should be reviewed page by page and section by section with the participant, or their legally authorized representative and their family members who they may wish to include in the conversation. It is recognized that this process may be time consuming and may take more than an hour to complete. The conversation should take place in a quiet, confidential and private area. The participant should not feel rushed or pressured by the conversation and should be confident of having an open dialogue with the principal investigator or designated individual. The potential participant should be offered the opportunity to ask questions and receive answers that satisfy those questions throughout the conversation.

After the informed consent discussion has occurred, the potential participant or legally authorized representative should be asked again if they wish to participate in the study. If the potential participant or legally authorized representative does want to participate, they will initial the bottom of each page of the informed consent document indicating the full document has been reviewed with them and they will sign the last page of the informed consent document where indicated. In addition to signing the consent, the potential participant or legally authorized representative should enter the date of signature on the consent document, to permit verification that consent was actually obtained before the participant began taking part in the study. The person obtaining informed consent must sign and date the document. The principal investigator must also sign and date the informed consent document. If the principal investigator does not conduct the informed consent discussion, the principal investigator must sign the informed consent document as soon as possible and no later than 10 days of the informed consent discussion taking place.

If consent is obtained the same day that the participants involvement in the study begins, the participants medical records/case report form should document that consent was obtained prior to participation in the research. This may be done by recording a time of informed consent and recording a time of the first study activity in an enrollment note. A copy of the signed informed consent document must be provided to the participant, a copy should be placed in the participants medical record along with an enrollment note and the original signed informed consent document should be retained in the master study records.

Witnessing the Informed Consent Discussion Process

Use of an Impartial Witness is necessary when either the participant or the participants legally authorized representative (LAR) speaks and understands English, but cannot read and write or is visually impaired. Persons who cannot read and write are considered illiterate. Visual impairments include blindness and other visual defects in which changes to the consent document, such as increased font size, are insufficient to allow the participant (or LAR) to read it. Use of an Impartial Witness is limited to situations in which the participant (or the participant’s LAR) comprehends spoken English and is able to communicate.

An Impartial Witness is one:

- "Who is independent of the trial?" This could be a person who is a family member. It would not be a member of the site staff involved with the study.
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- "Who cannot be unfairly influenced by people involved with the trial:" This would be a person free from potential coercion or undue influence or conflicted interest.

- "Who attends the informed consent process if the participant or the participants legally authorized representative cannot read:" This emphasizes the participation of the witness throughout the consent process, not just when the participant signs.

- "Who reads the informed consent form and any other written information supplied to the participant:" This responsibility has the witness confirming the participant was presented sufficient information to assure truly informed consent of the participant.

The purpose of the Impartial Witness signature is to attest to the fulfillment of the regulatory requirements as stated in 21 CFR 50.26. This includes affirming that the prospective participant was provided sufficient opportunity to consider whether or not to participate, that the possibility of coercion or undue influence was minimized, and that the information given to the participant was in language understandable to the participant or their legally authorized representative. The witness can further attest that the informed consent, whether oral or written, did not include any exculpatory language through which the participant was made to waive or appear to waive any of his/her legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

International Conference of Harmonization Good Clinical Practice further adds: "By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant’s legally acceptable representative, and that informed consent was freely given by the participant or the participant’s legally acceptable representative."

The Impartial Witness should sign and personally date the consent form after all of the following occur:

- The written informed consent document and any other written information provided to participant is read and explained to the participant (or the participants LAR)

- The participant (or the participants LAR) has orally consented to being part of the trial

- And, when capable of doing so, the participant (or the participants LAR) has signed (or made his/her "mark") and personally dated the informed consent form (when capable).

The use of an Impartial Witness may also be required when a potential participant is physically compromised. "A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. An enrollment note should document the method used for communication with the prospective participant and the specific means by which the prospective participant communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document."

Staff involved with the study should not serve as Impartial Witnesses. This, by extension, leaves relatives of the participant to serve as Impartial Witnesses. If a potential participant arrives without a family member but requires an Impartial Witness, the burden on a participant to return with a family member may be negated by the potential ability of a non-study staff member serving as the Impartial Witness. The Office of the IRB should be contacted in these situations to discuss who may best serve in this role prior to the informed consent discussion occurring.

Placement of the Impartial Witness signature line

Impartial Witness’ signature lines should be placed on the last page of the informed consent document after the participant’s line(s), and after the line of the person obtaining consent. When the study allows participants for whom an Impartial Witness may be necessary, having the Impartial Witness lines qualified as “if applicable” presents these lines consistently across all consent forms, avoids the need for an updated ICD and mitigates the temptation to make unapproved modifications to the ICD.

DEFINITIONS:
Impartial Witness: a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or the participant’s legally acceptable
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representative cannot read, and who reads the informed consent form and any other written information supplied to
the participant.

REFERENCE:
21 CFR 50.20, 50.25
45 CFR 46.116
45 CFR 46.109
45 CFR 46.111
21 CFR 50.20, 50.25 and 50.27
21 CFR 56.109, 56.111, and 312.62
FDA IRB Information Sheets: Guide to Informed Consent, 1998 located at
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm
FDA IRB Information Sheets: Frequently Asked Questions on Informed Consent
OHRP FAQs on Informed Consent located at http://answers.hhs.gov/ohrp/categories/1566

ATTACHMENTS:
IC 702-A Quick Reference Guide-Study Enrollment Note

PROCEDURE:

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Specialist/IRB Coordinator</td>
<td>1. Ensure most current approved IRB informed consent document is stamped with approval and expiration date and is provided to the investigator for use.</td>
</tr>
<tr>
<td>IRB Chairperson (or designee)</td>
<td>1. May audit the process of informed consent to ensure it is being conducted according to the expectations set forth in this policy.</td>
</tr>
<tr>
<td>IRB Committee</td>
<td>1. Must ensure the plan for the informed consent process and discussion are adequate. 2. May request audit of the informed consent process.</td>
</tr>
<tr>
<td>Investigator (or delegated individual)</td>
<td>1. Must provide a description of the informed consent process and discussion in the initial application. 2. Must perform the informed consent process as outlined in the above policy. 3. Must only use the most current IRB approved, stamped and current informed consent document. 4. Must sign the informed consent document at the time of the informed consent discussion unless responsibility is delegated to a key study personnel team member. If informed consent discussion is delegated, must sign the informed consent within 10 days of the informed consent discussion occurring.</td>
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CONCURRENT CONSENTS:

Institutional Official

Version Date 08/19/2015