



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Informed Consent – Process and Issues

INFORMED CONSENT – PROCESS and ISSUES

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1.0 Purpose

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To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the necessary elements of the informed consent process for the IRB.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

The IRB is charged with adequately safeguarding all human subjects involved in research. The informed consent process assures that prospective human subjects receive the information necessary to help them understand the nature of the research so they can knowledgeably and voluntarily decide whether or not to participate. As needed, the IRB office works with the Office of Sponsored Programs to clarify language in the consent such as publication, dissemination of information and participant language.

Administrative Office Review

To assist the Board in their duties, the Administrative Office of the IRB will also review all consent documents to determine:

- if they contain all of the required elements or
- Include adequate justification for a waiver of the elements.
- That the consent it is written in understandable language and format.

Board Review

The Board is charged with the review and approval of the consent document and the consent process to be used.

The consent document and process are reviewed for:

- 1) potential coercive influences:
 - person obtaining consent
 - location of consent discussion
 - timing of consent discussion
 - interval allowed for review of consent and discussion
 - content language of consent discussion outside of consent document
- 2) that the documents is written in understandable language and appropriate format
- 3) contains all required elements or justification for waiver or alteration

The Board reviews the process and/or document at initial review, continuing review and at any time there is a modification.

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Any suggestions or revisions to the consent that are requested by the Board will be communicated to the Principal Investigator.

The Board has the authority to request to be present and witness the consent process as performed with a potential participant at any time after indicating the desire to the Principal Investigator and study staff. Additionally the Board may delegate to the IRB Administrative office the authority to be present at an informed consent process on the Board's behalf.

Child Assent/Parent Consent

In determining applicability of Subpart D, the IRB will take into consideration the legal age for consent to treatments or procedures involved in the proposed research, under the applicable law of the jurisdiction in which the research will be conducted. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the IRB will consult with legal counsel to determine the legal age for the proposed treatments/procedures within the specific jurisdiction.

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#).

In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by [§46.116](#) of [Subpart A](#), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under [§46.404](#) or [§46.405](#). Where research is covered by [§46.406](#) and [§46.407](#) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

In determining who other than parent may consent on behalf of a child to their participation in research, the IRB will take into consideration who under the applicable law of the jurisdiction in which the research will be conducted meets the DHHS and FDA definition of a "guardian", that is who under the applicable law of the jurisdiction in which the research will be conducted is authorized to consent to general medical care on behalf of the child. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the

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IRB will consult with legal counsel to determine who is authorized to consent to general medical care on behalf of the child within the specific jurisdiction.

Per §46.408(c), In addition to the provisions for waiver contained in [§46.116](#) of [subpart A](#), the IRB may waive the requirements for parental consent if a determination is made that a research protocol is designed for conditions or subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects (i.e. neglected or abused children). This waiver is only allowed if consistent with all applicable federal, state and local laws. Additionally, an appropriate mechanism to protect the participating children must be substituted. A waiver of parental consent is not allowed for research regulated by the FDA.

A plan should be outlined to re-consent individuals who turn 18 while participating in research. At that time, they must be afforded the opportunity to consider their continued participation and to provide or deny consent.

Permission by parents or guardians shall be documented in accordance with and to the extent required by [§46.117](#) of [subpart A](#).

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Research Personnel Obtaining Consent

University of Missouri HealthCare policy (1-A-00) requires physicians to obtain consent for any medical or surgical procedure. Consent for research participation should be no less stringent. Therefore, for any significant risk, medical treatment study which would require that consent was obtained by a licensed physician outside the scope of research, consent for participation in the research study must be obtained by a physician listed and active as part of the study personnel. The types of research falling into this category includes medical or surgical intervention and dispensation of investigational or prescription drugs.

For those studies requiring that consent be obtained by a physician, the physician must at least present an overview of the project and answer any questions that the potential participant may have before the consent is signed. A coordinator working with the physician on the study may also be involved in the consent process and perform the detailed explanation of the study to the participant.

For significant risk, non-medical treatment studies, consent may be obtained by the non-physician PI or other qualified, active member of the study personnel. For all other types of research, such as minimal risk studies, consent must be obtained by a qualified, active member of the study personnel. For all studies, the person obtaining consent must be qualified and knowledgeable about the study to be able to answer any and all questions asked by the potential participant.

Under no circumstances should anyone who is not listed as study personnel and current with IRB training requirements obtain consent, interact with or access data of a potential study participant.

Passive Consent

The Federal Regulations do not recognize passive consent as an allowable consent option. Therefore, passive consent is not a viable consent option and should be avoided. If a passive consent process is felt to be in the best interest of the potential participant, a detailed description of the passive consent process and justification for its use must be submitted to the IRB for review on a case by case basis.

Telephone Consent

Consent obtained over the telephone is allowable but only under certain conditions. There are two viable options for obtaining telephone consent:

- 1) If written consent is required by the IRB, the IRB must look at the request for telephone consent and determine if it would be allowable. As a general rule with telephone consent and written documentation, the consent document must be sent (certified mail or fax) to the potential participant and then the consent process is conducted over the telephone with both parties reviewing the written documentation. The consent signed by the participant or participant's LAR must be received by the study before enrollment proceeds.
- 2) If waiver of documentation of consent is approved by the IRB, the information may be verbally presented to the potential participant over the telephone.

Faxed Consent

The use of a facsimile machine in obtaining written consent is allowable as long as it is used as a part of the complete consent process. The written consent document may be faxed to the potential participant for review. The participant must be contacted by telephone to allow the opportunity for questions. Once all information has been obtained to the satisfaction of the participant, the participant signed and dated consent form may be returned via fax.

Written Consent with Electronic Signature

The use of an electronic signature in lieu of a traditional handwritten signature will be accepted in the appropriate research context. Acceptable options of electronic consent include:

- 1) Research conducted in an online setting (interviews, surveys, social networking)
- 2) Any other context where it would not be suitable to obtain a handwritten signature (including signature on an electronic device)

Consent by Legally Authorized Representative

Research involving adults who are cognitively impaired or decisionally-impaired:

Cognitively-impaired or decisionally-impaired adults are individuals who have a diminished capacity for judgment and reasoning. Other individuals may be considered cognitively-impaired or decisionally-impaired or have limited decision-making ability because they are under the influence of drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill, or have disabling physical handicaps. In addition to considerations associated with the criteria for approval, the IRB will take into consideration the following additional points when reviewing research involving adults with impaired cognitive or decision-making capacity:

1. Adequacy of the proposed initial and ongoing consent and assent processes.
2. Who under state or local law meets the DHHS and FDA definition of “legally authorized representative” under the applicable law of the jurisdiction in which the research will be conducted. When the research will take place in jurisdictions outside of Missouri, (including other states and other nations), the IRB will consult with legal counsel to determine the requirements within the specific jurisdiction.

**For research at the VA, VA policy follows the law of the State of Missouri on research and legally authorized representatives. As needed, the HSIRB staff will consult with the VA compliance officer regarding legally authorized representatives.

Witness to Consent

A witness to the consent process is required under the International Code of Harmonization guidelines. However, if a potential participant is competent to understand the consent but is not able to read or sign his/her name, and independent witness must be present to view the consent process and obtaining of the consent. The witness must also sign the consent form as documentation of the witnessing.

Determination of Competency to Consent

When submitting a proposal to the IRB which includes incompetent individuals or when research is performed in a population where competency may be in question, the investigator must provide to the IRB a detailed plan to determine competency of the potential participant to offer valid informed consent, whether consent must be obtained from the participant’s legally authorized representative, and/or assent.

Consent within a Veteran’s Hospital Facility

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When research is to be conducted using hospital or clinic patients in the Harry S Truman Memorial Veteran's Hospital, special consent procedures must be used. Please refer to the HS IRB policy on VA and the Harry Truman policies and investigator's manual (<http://www.research.va.gov/resources/policies/default.cfm>).

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4.0 Related SOP

Informed Consent – Types and Elements
Hospital Policy I-A