INFORMED CONSENT – PROCESS and ISSUES

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Approved By: Robert Hall, PhD
Associate Vice Chancellor, Research

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Related SOP

1.0 Purpose

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 Health Sciences IRB.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.
3.0 Policy/Procedure

The HS 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.

Board Review

The Board is charged with the review and approval of the consent procedure to be used. The Board must review and document approval of the timing and place at which the consent process will occur. The Board will ensure that participants or their legally authorized representative are given adequate time to read the consent and ask questions prior to signing the consent.

In addition to the language contained in the consent form, the consent procedure process may not lead to possible coercion of the potential participant. Coercive influences may include:

1) person obtaining consent
2) location of consent discussion
3) timing of consent discussion
4) interval allowed for review of consent and discussion
5) content language of consent discussion outside of consent document

Additionally, the Board must review and document approval that the consent contains all of the required elements or there is adequate justification for a waiver of the elements. The Board must also review the consent to determine and document that it is written in understandable language and format.

In addition to the review of the consent process, the Board must review the consent document, written summary and/or oral consent checklist to determine the appropriateness of the presented material. The Board may review the consent process and document at any time but must review the process and/or document at initial review, continuing review and at any time that an unanticipated problem, amendment or other actions may have changed the risk/benefit ratio to necessitate revision of the consent procedure or document.

Any suggestions or revisions to the consent that are requested by the Board will be communicated by the Board to the IRB administrative office who will then forward the requests 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 HS IRB Administrative office the authority to be present at an informed consent process discussion on the Board’s behalf.

The Board has the authority to request additional safeguards be implemented to protect the rights and welfare of vulnerable subjects.

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. The administrative office will also review the consent to determine that it is written in understandable language and format.

The Administrative Office will review all submitted consent forms, written summaries and/or oral consent checklists to determine if they are written in appropriate language and format and also to determine if they adhere to federal regulations regarding required content. The information in the consent form will be compared with information provided in the application and study protocol to determine if all information necessary to enable the participant to make an informed decision about the study is being conveyed to the potential participant.

The Administrative Office will conduct this review of the consent at any time but must review the document at initial review, continuing review and at any time that an unanticipated problem or amendment may have changed the risk/benefit ratio to necessitate revision of the consent procedure or document.

Any issues found during the administrative review of the consent will be forwarded to the IRB reviewer.

**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.

Whenever children are recruited as research subjects, the IRB must decide and document whether child assent is required for this project and determine that adequate provisions are made for soliciting the assent of the child when, in the judgment of the IRB, the children are capable of providing assent. The HS IRB has historically decided that the age at which a child will understand and be able to communicate assent by signature is the age of seven (7). However the HS IRB looks at each individual study and what is required of the child and also relies on the judgment of the investigator to determine the understanding and maturity level of the child in obtaining verbal assent.

Per §46.408 and 21 CFR 50.55, 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. The IRB may waive the requirement for child assent if it deems the children’s capability is limited to the point they can not reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that it is important to the health or well-being of the children and is available only in the context of the research. Even when the IRB determines the participants are capable of assent, the IRB may still waive the assent requirements under the same circumstances as outlined for waiver or alteration of informed consent (§46.116 of Subpart A) or as outlined in 21 CFR 50.55.

The IRB must also determine that adequate provisions are made to solicit the consent of the child’s parent(s) or guardian(s).
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 IRB will consult with legal counsel to determine the who is authorized to consent to general medical care on behalf of the child within the specific jurisdiction.

There are four categories of research involving children. Each level has a parental/guardian signatory requirement.

If assent is required, the child must sign the consent form signifying understanding of the project and assent to participate in the research project. The IRB must also determine the child risk category of the proposed research which determines the parental signatory authority. The child category definitions and corresponding parental signatory requirements are as follows:

- 45 CFR 46.404 or 21 CFR 50.51 Research not involving greater than minimal risk - 1 parent may be sufficient
- 45 CFR 46.405 or 21 CFR 50.52 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects – 1 parent may be sufficient
- 45 CFR 46.406 or 21 CFR 50.53 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition – 2 parent
- 45 CFR 46.407 or 21 CFR 50.54 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children – 2 parent

For those category requiring consent of 2 parents, it is required unless one parent is not reasonably available, deceased, unknown, incompetent or when only one (1) parent has legal responsibility for the care and custody of the child.

Per §46.408(c), 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 reconsent 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.

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 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.

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.

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 HS 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.

Waiver of documentation of informed consent

Written documentation of informed consent may be waived by the IRB if either of the following apply:

a) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context*;
b) The informed consent is the only record linking the subject to the research, the harm from the possible breach of confidentiality is the principal risk to the subject and each participant will be asked whether the participant wanted documentation linking the participant with the research, and the participant’s wishes would govern.

*If the study is regulated by the FDA this is the only option for allowing a waiver of documentation of consent.

**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.

**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. 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 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 and the VA policy. 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 HS 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

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.va.gov/columbia-mo/humanres/index.shtml)

4.0 Related SOP

Informed Consent – Types and Elements
Hospital Policy I-A