Governors State University

Institutional Review Board
Room G353
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SOP: Informed Consent, Assent, and Parental Permission

1. PURPOSE

1.1. The purpose of this guidance is to clarify the Governors State University ("GSU" or the "University") Institutional Review Board's ("IRB") requirements for obtaining informed consent, assent, and parental permission from human subjects of non-exempt research.

2. GUIDANCE

2.1. General Informed Consent

2.1.1. The IRB requires researchers to conduct a legally effective informed consent process with each potential human research subject (or his or her guardian) before the subject may be enrolled in a research study (45 CFR 46.116; 21 CFR 50.20). It is the ultimate responsibility of the Principal Investigator (PI) to ensure that informed consent is obtained from each human subject and that the consent process is conducted as detailed in the approved research protocol.

2.1.2. The requirement of informed consent is founded on the principle of respect for persons, one of the three fundamental ethical principles of human subjects research, described in the Belmont Report. The informed consent process ensures that the subjects are given the opportunity to decide knowingly and voluntarily whether or not to participate in the research.

2.1.3. The informed consent process is an essential and continuous communication process between the prospective human subject and a researcher that begins with the initial approach of a researcher to the potential subject and continues through the completion of the research study. It is the process by which the researcher explains the study to the potential subject, provides the subject with an opportunity to ask questions, and then obtains the subject's voluntary agreement to participate in the research.

2.1.4. An informed consent document is used to provide subjects with the information they need to make a decision to volunteer for a research study. The document must present information in sufficient detail and must be organized in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's understanding of the reasons why they might or might not want to participate in the research.

2.1.5. The informed consent document for subjects recruited from the general population should be written at an 8th grade level.

2.1.6. Although federal regulations (45 CFR 46.116) provide the framework for the type of information that must be included in the informed consent form, the IRB

has the final authority about the content of the consent document presented to the prospective subjects. The IRB may require that the document includes information that the IRB considers to be significant and meaningful for the protection of the subjects' rights and welfare. The IRB also has the authority to observe, or to request a third party to observe, the consent process.

2.1.7. The consent document must be signed and dated by the subject or the subject's guardian prior to any data collection activities. The original signed consent form must be kept in a secure virtual or physical place at the PI's site for at least three years after completion of the research for auditing purposes.

2.1.8. The IRB has the authority to waive documentation of informed consent as detailed in 45 CFR 46.117. If a waiver of documentation of consent is granted, the subject must be given a copy of the consent form.

2.1.9. While there are a few circumstances in which the IRB may grant a waiver or provide for an alternative to the informed consent process, as detailed in 45 CFR 46.116 (f) and 45 CFR 46.117, obtaining legally effective, written informed consent is the standard for non-exempt research with human subjects.

2.2. **Informed Consent of Non-English-Speaking Subjects**

2.2.1. There may be circumstances when a potential subject does not speak English. Investigators must deliver all information regarding informed consent to a potential subject or their legally authorized representative in the subject's native language(s) or one in which the subject is fluent. The investigator must provide a prospective subject with a translated version of the consent form. In cases of research studies that are deemed greater than minimal risk, the presence of a translator may be required during the consent process to ensure culturally competent communication.

2.2.2. A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.

2.3. **Informed Consent of Decisionally Impaired and Vulnerable Individuals**[i]

2.3.1. Decisionally impaired individuals cannot give consent. Other vulnerable individuals, including terminally ill or persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. For such individuals, a participant-designated or state-specified legally authorized representative (LAR) can give consent to participate in research. Absent a participant-designated or state-specified LAR for research decision making, investigators may use, and the IRB may approve as surrogates individuals who are specified in state statutes as LARs for medical decision making, or, in the absence of such statues, individuals who would normally provide consent for medical care under prevailing, commonly accepted clinical practices. The State of Illinois does not have specific guidance on legally authorized representatives for research purposes. For research conducted in Illinois, the IRB will follow the Health Care Surrogate Act (755 ICLS 40/) for

guidance in determining who may serve as the surrogate for research consent. The following persons, in order of priority, may serve as the surrogate for research consent: 1) The subject's guardian, 2) The subject's spouse, 3) Any adult son or daughter of the subject, 4) Either parent of the subject, 5) Any adult brother or sister of the subject, 6) Any adult grandchild of the subject, 7) A close friend of the subject, 8) The subject's guardian of the estate. The researcher has the right to rely on any of the above persons to provide surrogate permission if the researcher believes, after reasonable inquiry, that a surrogate of higher priority is not available.

2.3.2. Additionally, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards shall be included in the study to protect the rights and welfare of these subjects.

3. Child Assent[ii]

3.1. Children (minors) are a vulnerable research population and, as such, require additional protections when they engage as research subjects. Subpart D of both 45 CFR 46 (DHHS), and 21 CFR 50 (FDA) require certain additional protections for children involved as subjects in research. Specifically, 45 CFR 46.408(a) requires that adequate provisions be made for soliciting the assent of children involved in research, when the children are capable of providing assent. In determining whether children are capable of assenting, the ages, maturity, and psychological state of the children should be taken into account.

3.2. In general, children should be given developmentally appropriate information about a research study in a language and manner that is understandable to them, given their age, maturity, and cognitive abilities.

3.3. When the duration of children's participation in a research project will likely continue into majority age, the investigator must include provisions for obtaining the legally effective consent from the now-majority age (adult) subject for proceeding with their research participation.

3.4. Children aged 12-17 years: Children in this age group should be fully informed about the research and provide documented assent. In some cases, the child may verbally assent to participate in the study. In any case, the information provided to the child should be appropriate to the level of understanding, as influenced by the child's age, maturity, and developmental abilities. Assent must be obtained along with the permission of a parent or guardian.

3.5. Children aged 7-11 years: This age group should be fully informed about the research, using language appropriate to their level of understanding, as influenced by the child's age, maturity, and developmental abilities. Further, assent should be obtained verbally or in writing from those deemed capable of making a meaningful decision. Assent should be obtained along with the permission of a parent or guardian.

3.6. Children under the age of 7: Minors under 7 years old should provide verbal assent. The verbal assent script should be conversational and stated in such a way that is

understandable and age appropriate. Assent should be obtained along with the permission of a parent or guardian.

3.7. When assent is required by the IRB, the decision of the child assenting is binding, provided parental or guardian permission, when necessary, has been obtained.

3.8. The assent of a child may be waived if the IRB determines and provides protocol specific information documenting that:

3.8.1. Children are not capable of providing assent based on their age, maturity, or psychological state;

3.8.2. The capability of some or all of the children is so limited that they cannot reasonably be consulted; or

3.8.3. 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 child and is available only in the context of the research.

3.9. A decision by the IRB that the children are capable of assenting does not prevent the IRB from waiving assent under the conditions specified in 45 CFR 46.116(f).

3.10. Even where the IRB approves a waiver of assent, it is generally desirable to still provide the child with an understanding of the research. The IRB may require the investigator to prepare an "information sheet" that provides the child with an explanation of the study in a format and language appropriate for the child's level of understanding, as influenced by the child's age, maturity, and developmental abilities, experience, and condition.

4. **Permission from Parents or Guardians**

4.1. 45 CFR 46.408(b) requires that adequate provisions be made for soliciting the permission of parents or guardians of each child involved in a research study. All of the requirements concerning informed consent apply to obtaining parental permission and the appropriate elements of consent must be included in a written parental permission document.

4.2. The IRB may waive the requirement for obtaining permission from parents or guardians when the research meets the provisions for waiver in 45 CFR 46.116(f) or the IRB determines that the research is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). The waiver must be consistent with federal, state, or local law.

5. PROCEDURES

5.1. The GSU IRB provides informed consent (assent, permission) templates, available on the IRB website. Investigators should use the templates as a guide for developing the informed consent (assent, permission) document for their study.

5.2. The PI submits an IRB application which includes a description of the proposed informed consent (assent, permission) procedure and consent (assent, permission) document.

5.3. The IRB application must indicate which study personnel will participate in the informed consent (assent, permission) process.

5.4. Non-English translations of the consent document must be accompanied by a translator statement attesting to the accuracy of translation.
5.5. The IRB will assess the PI's description of the informed consent (assent, permission) procedure to ensure that all applicable regulatory requirements are met.
5.6. The IRB will review the proposed informed consent (assent, permission) document to ensure that all applicable regulatory requirements are met.
5.7. IRB approved consent forms must include a stamp or a statement of approval including the protocol number and date. Investigators may only enroll subjects using IRB approved informed consent forms.
5.8. Any substantive changes to the consent document made by a researcher must be submitted to the IRB for review and approval.

REGULATIONS
45 CFR 46.116, 45 CFR 46.117, 45 CFR 46.408, 21 CFR 50.20

AUTHOR REFERENCES
Adapted from the George Mason University IRB SOP 2.2.1 "Informed Consent, Assent, Parental Permission, and Documentation," the University of Illinois Chicago IRB SOP 2.3 "Informed Consent Process and Documentation," and the Northern Illinois University IRB POLICY ON RESEARCH PARTICIPATION OF INDIVIDUALS WITH IMPAIRED CONSENT CAPACITY

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DISCLAIMER
The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Institutional Official calls for review. Requests for exception to any portion of this SOP must be presented in writing to the Institutional Official.

[i] This SOP does not cover the consent process for prisoners and children who are wards of the state.
[ii] Circumstances when minors can consent for themselves are described in 325 ILCS 45/2(c) and 410 ILCS 210. A minor who is able to give consent under Illinois State Law is not considered a child under federal regulations.