KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Informed Consent Process for Research
Last Updated	11/16/2021
Responsible Office	IRB Office
Contact Information	IRB Office Email: irb@kennesaw.edu Phone: 470-578-4941

1. Purpose:

Informed consent is one of the primary ethical requirements underpinning human research; it reflects the basic principle of respect for persons outlined in the Belmont Report. Informed consent is not a single event but an ongoing process, designed to provide potential research participants with sufficient information to make a fully informed, autonomous decision about research participation. This policy describes the ethical and regulatory requirements for the consent process, and the criteria for waiver or alteration of consent and waiver of documentation of consent.

This policy applies to all non-exempt research (i.e., studies reviewed by the convened IRB or expedited procedure) except where otherwise stated.

2. DEFINITIONS

Consent Process: is an active ongoing process that involves more than the documentation of consent. The process involves an information exchange and on-going communication that takes place between the investigator(s) and the prospective participant.

Informed Consent: is the agreement to participate in research expressed by an adult person (or by the legally authorized representative (LAR) for a child or for an adult with cognitive impairment, based on sufficient information and adequate opportunity to consider voluntary participation. Also referred to as legally effective informed consent.

Adult**:** a person who by virtue of attaining a certain age is regarded in the eyes of the law as being able to manage his or her own affairs. For the purposes of this policy, adult status is defined by the laws governing the location where the research will take place. In Georgia, an adult is an individual who is 18 years of age or older.

Exculpatory Language: as it applies to informed consent, is any written or verbal communication which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

3. Policy

3.1. Before involving a human participant in research, the investigator must obtain the informed consent of the potential participant or the participant's Legally Authorized Representative (LAR), unless the requirement for consent has been waived or altered by the IRB.

3.2. Consent must be sought under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether to participate.

3.3. Consent must be sought under circumstances that minimize the possibility of coercion or undue influence.
3.4. The information provided during the consent process must be presented in language understandable to the participant or the LAR.
    3.4.1. Guidance from our federal oversight office, OHRP, states that "Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject." Based on this, the IRB requests that consent documents use second person.
    3.4.2. Consent documents should have a readability level appropriate for the participants. The IRB recommends that consent documents intended for the general population be written for an 8th- grade reading comprehension level. Use of academic, legal, or scientific/technical terms is not appropriate for this level.
    3.4.3. Consent documents should be written in the language in which the participant is literate. If the participant/representative understands more than one language, the consent process should be conducted, whenever possible, in the preferred language of the participant/LAR.
3.5. No informed consent may include any exculpatory language through which the participant or the LAR is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
3.6. The prospective participant or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate. Informed consent as a whole must present information relating to the research in sufficient detail, and the information must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or LAR's understanding of the reasons why one might or might not want to participate.
3.7. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
3.8. Key information includes, but is not necessarily limited to, the following:
    3.8.1. The fact that consent is being sought for research and that participation is voluntary;
    3.8.2. The purposes of the research, the expected duration of the prospective participant's participation, and the procedures to be followed in the research;
    3.8.3. The reasonably foreseeable risks or discomforts to the prospective participant;
    3.8.4. The benefits to the prospective participant and/or to others that may reasonably be expected from the research; and
    3.8.5. Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective participant
3.9. When student educational records are involved, the requirements of the Family Educational Rights and Privacy Act (FERPA) that pertain to written permission must be applied.
3.10. Only approved members of the study team may be involved in obtaining consent from potential participants as this activity constitutes engagement in research.
3.11. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purposes of screening, recruiting, or determining the eligibility of

prospective participants for inclusion in the research without the informed consent of the prospective participant or the participant's LAR if either of the following conditions is met:

3.11.1. The investigator will obtain information through oral or written communication with the prospective participant or LAR, or

3.11.2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

3.12. When either of the above conditions is met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe these activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a participant in other research activities, including the use of a participant's identifiable private information or biospecimens.

3.13. The waiver request described next is required for all non-exempt studies that involve deception or incomplete disclosure. Other examples for use of this waiver may include studies involving medical chart review and secondary data analysis.

3.14. The IRB may approve a consent or parental permission procedure which does not include, or which alters, some or all of the elements of informed consent, or waives the requirement to obtain informed consent if it finds and documents that:

3.14.1. the research is not FDA-regulated,

3.14.2. the research does not involve non-viable neonates, and

3.14.3. all the following criteria are met:

3.14.3.1. The research involves no more than minimal risk to the participants.

3.14.3.2. The research could not practicably be carried out without the waiver or alteration

3.14.3.3. The waiver or alteration will not adversely affect the rights and welfare of the participants.

3.14.3.4. Whenever appropriate, the participants or LARs will be provided with additional pertinent information after participation.

3.15. Use of "passive" or "opt-out" consent can only be approved if a waiver or alteration has been proposed and meets the criteria in section 2.11

3.16. Documentation of informed consent is required in all cases unless the IRB has approved a waiver of the requirement to document informed consent per 45 CFR 46.117(c).

4. SPECIFIC CONSIDERATIONS IN INFORMED CONSENT

4.1. Informed consent must be obtained from:

4.1.1. The participant when the participant is an adult capable of providing consent.

4.1.1.1. When the targeted population may include adults with cognitive impairment, there must be an adequate plan for the assessment of the capacity to consent.

4.1.2. The LAR when the participant is of diminished capacity to consent.

4.1.2.1. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.

4.1.2.2. LARs are to be well informed regarding their roles and obligations to protect incompetent participants or participants with impaired decision-making capacity. They must also be told their obligation is to try to determine what the prospective

participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent participant's best interest.

4.1.3. One or both biologic or adoptive parents (parental permission) and the child (assent) when the participant is a child, or in the absence of a parent, a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

4.1.3.1. The IRB must have specifically approved the protocol to allow the enrollment of children.

4.1.3.2. The principal investigator must determine the appropriate age of consent for research, even if the participant is considered to be an adult for purposes of medical treatment. This will be determined by the laws governing the location where the research will take place. (e.g., the legal age of consent in Georgia is 18.)

4.1.3.3. The only exceptions to this requirement would be if the state considers the participant to be an adult, such as in the case of emancipated child.

4.1.3.4. Assent must be sought from the child unless the IRB has waived this requirement for either of the following reasons.

4.1.3.4.1. The child is incapable of providing assent (due to age or condition); or

4.1.3.4.2. The intervention holds out the prospect of direct benefit to the child, and the intervention is available only in the context of the study.

4.1.3.4.3. In these two situations, permission from parent(s) is sufficient.

4.1.3.5. Permission is obtained from both parents unless: one parent is deceased, unknown, incompetent, or not reasonably available; only one parent has legal responsibility for the care and custody of the child; or the IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

4.1.3.6. If a child participant attains the age of consent while the research is ongoing/research activities continue (e.g., collection of data, analysis of individually identifiable data), the investigator must seek the informed consent of the now-adult participant in order to continue his/her inclusion in the project, unless the IRB has approved a waiver of the requirement to obtain informed consent.

5. **PROCEDURES**: **Investigators**

5.1. The investigator(s) must ensure that research participants provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered.

5.2. The project submission must describe the detailed process for obtaining consent: how, where and when consent will be sought, the language understood by the prospective participant or the LAR (if not English), the language used by those obtaining consent (if not English), and the study team member(s) who will be responsible for obtaining consent.

5.3. The consent process should:

5.3.1. Invite and answer the participant's questions.

5.3.2. Give the participant sufficient time to discuss taking part in the research study with family members, friends, and other care providers, as appropriate. Invite and encourage the

participant to take the written information home to consider and discuss the information and the question of whether to participate with family members and others before making a decision

5.3.3. Be conducted in a language understandable to the participant.

5.3.4. When appropriate, include a process to determine whether all of the following are true, and if not, to either continue the explanation or determine that the participant is incapable of consent (Note: If the study is a clinical trial and the investigator is not a physician or physician extender, the study physician or physician extender may assist with these steps).

5.3.4.1. The participant understands the information provided.

5.3.4.2. The participant does not feel pressured by time or other factors to make a decision.

5.3.4.3. The participant understands that there is a voluntary choice to make.

5.3.4.4. The participant is capable of making and communicating an informed choice.

5.3.5. Provide objective information and avoid statements that imply that compensation or treatment is never available when the participant has questions about treatments or compensation for injury.

5.3.6. Stop if a participant indicates that he or she does not want to take part in the research study.

5.4. The participant and the individual obtaining consent must sign and date the consent document unless the IRB waives the requirement for written documentation of the consent process.

5.4.1. Participants who are unable to read or write can provide documentation of consent by making a mark in place of a signature on the consent document, when consistent with any applicable local law.

5.5. Provide a copy of the signed document to the participant.

References:

45 CFR 46.116
45 CFR 46.117
21 CFR 50
A Guide on Informed Consent - FDA
Informed Consent for Clinical Trials - FDA
Informed Consent - HHS
Informed Consent FAQs - HHS
FERPA
What must a consent to disclose educational records contain - FERPA
KSU Consent Templates

Appendix

Basic Elements for Informed Consent

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- **Research, Rights or Injury:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional Elements as Appropriate

- A statement that the 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
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- 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
- The approximate number of subjects involved in the study