Informed Consent Process for Research

1. PURPOSE

1.1. 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 subjects 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.

2. DEFINITIONS

2.1. Consent Process: is an active ongoing process that involves more than the documentation of consent. The process involves an information exchange and ongoing communication that takes place between the researcher(s) and the prospective subject.

2.2. Informed Consent: is the agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information and adequate opportunity to consider voluntary participation. Also referred to as legally effective informed consent.

2.3. 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, an adult is defined in the location where the research will take place. In Georgia, an adult is an individual who is 18 years of age or older.

2.4. 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. This policy applies to studies reviewed by the convened IRB or expedited procedure (i.e., non-exempt research; see Policy and Procedures: Exempt Determination).

3.2. The process for obtaining consent must incorporate all of the following:

3.2.1. The researcher will obtain the informed consent of the potential subject or the subject's legally authorized representative, unless the requirement for consent has been waived or altered by the IRB.

3.2.2. Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.

3.2.3. Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence.
3.2.4. The information provided during the consent process will be presented in language understandable to the subject or the subject’s representative.

3.2.5. The information being communicated during the consent process is free of exculpatory language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

4. SPECIFIC CONSIDERATIONS IN INFORMED CONSENT

4.1. Language and readability must be appropriate for the subjects. Consent documents should be written in second person as use of first person can be interpreted as suggestive. Use of scientific/technical terms and legalese is not appropriate. The IRB recommends that consent documents intended for the general population be written for an 8th grade comprehension level.

4.1.1. If the subject/representative understands more than one language, consent process should be conducted, whenever possible, in the preferred language of the subject/representative.

4.2. Informed consent must be obtained from:

4.2.1. The subject when the subject is an adult capable of providing consent.

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

4.2.2. Legally authorized representative when the subject with diminished capacity to consent. See Section 2.1 of Policy and Procedures: Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children.

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

4.2.2.2. Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons 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 person’s best interest.

4.2.3. One or both biologic or adoptive parents (parental permission) and the child (assent) when the subject 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.

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

4.2.3.2. 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, etc. This will be determined by the location where the research will take place. (e.g., the legal age of consent in Georgia is 18.)
4.2.3.3. 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. See Section 2.2 of Policy and Procedures: Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children.

4.2.3.4. Assent must be sought from the child unless the IRB has waived this requirement for one of the following reasons: 1) the child is incapable of providing assent (due to age or condition), or 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. In these two situations, permission from parent(s) is sufficient.

4.2.3.5. 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.

4.2.3.6. When participants are children and the data are sensitive, Protection of Pupil Rights Amendment (PPRA) must be applied.

4.2.3.7. 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 their inclusion in the project, unless the IRB has approved a waiver of the requirement to obtain informed consent.

4.2.3.8. When student educational records are involved, the requirements of the Family Educational Rights and Privacy Act (FERPA) must be applied.

4.3. Only approved members of the study team may be involved in obtaining consent from potential participants as this activity constitutes engagement in research.

4.4. The consent process must include presentation of all of the required elements of consent (see Checklist: Informed Consent Elements), and any additional elements that the IRB determines may be required for the specific project.

4.5. 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 to waive the requirement to obtain informed consent if it finds that: the research is not FDA-regulated, the research does not involve non-viable neonates, and all the following four criteria are met:

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

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

4.5.3. The research could not practically be carried out without the waiver or alteration.

4.5.4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
5. PROCEDURES: Researchers

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

5.2. The principal investigator must describe to the IRB the detailed process for obtaining consent: how, where, and when this will occur and the study team member(s) who will be responsible for this.

5.3. Invite and answer the subject questions.

5.4. Give the subject sufficient time to discuss taking part in the research study with family members, friends, and other care providers, as appropriate. Invite and encourage the subject to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

5.5. When appropriate, ask the subject questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject 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):

5.5.1. The subject understands the information provided.

5.5.2. The subject does not feel pressured by time or other factors to make a decision.

5.5.3. The subject understands that there is a voluntary choice to make.

5.5.4. The subject is capable of making and communicating an informed choice.

5.6. If the subject has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.7. If a subject indicates that he or she does not want to take part in the research study, this process stops.

5.8. The subject and the individual obtaining consent signs and dates the consent document unless the requirement for written documentation of the consent process has been waived by the IRB. See Policy and Procedures: Documentation of Informed Consent.
5.8.1. Subjects 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.

5.9. Provide a copy of the signed document to the subject.

6. **PROCEDURES: Institutional Review Board**

6.1. The IRB Reviewer will ensure that the required and appropriate additional elements of disclosure have been included in the information that will be presented to the potential participants. The elements must be sufficiently complete and appropriate; the use of templates and suggested verbatim language or by investigator-created language equivalent in meaning to the verbatim template language is highly recommended.

6.2. If a waiver or alteration of the elements of informed consent or a waiver of the requirement to document informed consent has been requested by the investigator, the IRB Reviewer will determine if the justification is adequate to grant the waiver, and will document its findings via the appropriate checklists (the justification/findings must document why the IRB judged that each criterion was met for the specific protocol and may reference other parts of the submission to supplement the justification provided by the researcher).

7. **MATERIALS**

7.1. Checklist: Informed Consent Elements
7.2. Checklist: Waiver or Alteration of the Consent Process
7.3. Checklist: Waiver of Written Documentation of the Consent Process

8. **REFERENCES**

8.1. Belmont Report
8.2. 21 CFR §50.20, 50.25
8.3. 45 CFR §46.116
8.4. Policy and Procedures: Deception or Incomplete Disclosure
8.5. Policy and Procedures: Documentation of Informed Consent
8.6. Policy and Procedures: Exempt Determination
8.7. Policy and Procedures: Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children