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 ongoing communication 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

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.

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 oth

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 th i e a feoiTenf4th4e44olpadeor.

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

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