SOP 704: ASSENT

PURPOSE

The University of Utah Institutional Review Board (IRB) follows the regulatory requirements for making adequate provisions to obtain the assent of children in research as outlined in this policy. Additionally, the University of Utah IRB requires adequate provisions be made to obtain the assent of adults with diminished decision-making capability, as outlined in this policy.

SCOPE

This policy applies to non-exempt human subject research conducted at the University of Utah.

DEFINITIONS

A. ***Assent*** means a participant's affirmative agreement to participate in research. Mere failure to object absent affirmative agreement, should not be construed as assent.

POLICY

The principle of "respect for persons" requires that the choice of an autonomous person be respected. Under the usual conditions of research, this is accomplished by soliciting the informed consent of the prospective research participant. In the case of an adult with diminished decision-making capacity or non-autonomous child, applying the principle of respect for persons is problematic. Therefore, permission of either the parent or legally authorized representative is required (see SOP 701: General Requirements of Informed Consent). However, individuals capable of some degree of understanding (generally, a child of seven or older, or an adult with diminished decision-making capacity) should participate in research only if they assent. When assent is required by the IRB, if the individual dissents from participating in research, the individual's decision should be respected.

In instances where the participant is a child or where the participant has diminished decision-making capacity, the IRB must find that adequate provisions are made for soliciting the assent of the participant, when in the judgment of the IRB the participant is capable of providing assent.

In determining whether participants are capable of assenting, the investigator and the IRB considers the age, maturity, and psychological state of the participant involved. This judgment may be made for all participants under a particular protocol, or for each participant, as the IRB deems appropriate. The assent of the participant is not a necessary condition for proceeding with the research if the IRB determines:

1. The capability of some or all of the participants is so limited that they cannot reasonably be consulted;
2. 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 participant and is available only in the context of the research;

3. The research meets the same conditions as those for waiver or alteration of informed consent in research (see SOP 703: Waiver or Alteration of Informed Consent).

Informed consent is an on-going process throughout the duration of a research project. When a child who was enrolled in research with parental/guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the investigator should seek and obtain legally effective informed consent, as described in SOP 701: General Requirements of Informed Consent for the now-adult participant for any ongoing interactions or interventions with the participants unless the IRB determines that the requirements for obtaining informed consent can be waived. Prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult participant.

The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent.

For those participants who may recover an adequate amount of decision-making capacity during the course of the study, the IRB will consider plans to obtain full informed consent from the participant.

PROCEDURES

1. Assent for Children

1.1. If children capable of some degree of understanding (generally, age seven or older) are involved in a proposed study, investigators must provide the IRB with a plan to obtain assent or justification why assent is not required.

1.2. The IRB determines whether all, none, or some of the children are capable of assent. If assent is required not required for some or all of the children, justification is documented in the reviewer checklist (children checklist).

1.3. If the IRB determines that assent is a requirement for some or all of the children, the IRB determines and documents in the reviewer checklist (assent checklist) whether the proposed assent process is acceptable and whether documentation of assent is required.

2. Assent for Participants with Diminished Decision-Making Capability

1.1. If individuals with impaired decision-making capacity are involved in a proposed study, investigators should provide the IRB with a plan to obtain assent or justification why assent is not required.

1.2. The IRB determines whether an assent process should be included along with the informed consent from a legally authorized representative (LAR). If assent is required, additional considerations are made regarding whether a re-assenting process should occur and whether obtaining full informed consent from the participant may occur should they recover an adequate amount of decision-making capacity. Determinations are made in the reviewer checklist.