HUMAN RESEARCH PROTECTION PROGRAM POLICY AND PROCEDURE

3.2 INFORMED CONSENT BY SURROGATE (PARENTS OR LEGALLY AUTHORIZED REPRESENTATIVES)

RESPONSIBLE OFFICE: HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENT (HRPPD) **EFFECTIVE DATE: June 7, 2021**

I. POLICY RATIONALE AND TEXT

A. Obtaining legally effective informed consent of individuals before involving them in research is one of the central protections provided in the regulations governing research. Informed consent in research is founded on the Belmont Principle "respect for persons"

B. This policy is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct research on problems that are unique to persons who have impaired decision-making capacity.

C. Ordinarily, an investigator must obtain informed consent directly from prospective research subjects. When the prospective research subject is a child or an adult whose own consent would not be legally effective because they lack the capacity to comprehend and give or communicate their informed consent, then research may be conducted only with the consent of the potential subject's parent, guardian or legally authorized representative (the "LAR"), which is also known as "surrogate consent."

D. The UTSW IRB may waive the requirement for obtaining surrogate consent (from a parent, legal guardian, or LAR) if the research meets the provisions for waiver in 45 CFR 46.116(f)(3)(i-v) (see 3.3 INFORMED CONSENT WAIVERS AND ALTERATIONS)

E. Assent (affirmative agreement) is required if the subject is able to give it. However, the IRB may waive the requirement to seek assent if the subject is not competent to give it.

II. SCOPE

A. This policy and procedure applies to all human subjects' research involving children and decisionally impaired or otherwise incompetent adults.

III. PROCEDURES FOR POLICY IMPLEMENTATION

A. Assent - The PI must develop processes and forms consistent with guidance provided in several IRB forms and policies: 2.6 RESEARCH INVOLVING INDIVIDUALS WITH DIMINISHED AUTONOMOUS DECISION-MAKING CAPACITY, eIRB smart form, 6.2 IRB APPROVAL OF RESEARCH and 2.1. INITIAL REVIEW OF RESEARCH policies concerning review related to assent. The PI is responsible for including in the IRB application a description of the process/procedure for obtaining and documenting assent when research includes:

1. Minors (Children)

    a. In the state of Texas, a minor is a person who is under the age of 18. This may vary within the U.S. and across the world.

    b. Because "assent" means an affirmative agreement to participate in research, (45 CFR 46.402(b)), the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

    c. When judging whether children are capable of assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be

made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

d. The IRB reviews the proposed process and, if applicable, the assent process to ensure compliance with IRB guidance and federal requirements. In general in determining whether assent of children is required in all, some or none of the children in a study the IRB is guided by the following age ranges:

   i. Ages 0-6 – The capability of children of this age group is so limited that they cannot reasonably be consulted. Assent is not required.

   ii. Ages 7-10 – Children of this age group may be capable of providing assent depending on the maturity and psychological state of the children involved in the research. Verbal or written assent may be required but must not be waived by the IRB if the child is unable to provide assent.

   iii. Ages 10 – 17 – Children of this age group are expected to be capable of providing assent. Written assent is usually required unless waived by the IRB.

e. If assent is determined appropriate the investigator must obtain assent from minors he/she deems capable of understanding the nature and consequences of participation in the study regardless of the age. The child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

f. If assent is determined appropriate, documentation of assent is required. Generally, assent of the child is documented by having the child sign the consent form in the designated signature section.

g. If a child is enrolled onto a study and turns 10 while actively participating on a study, written assent must not be documented. However, the study team should continue the consent conversation with the child and parent/guardian throughout the study.

h. The IRB may waive its requirements for obtaining or documenting assent if the IRB determines:

   i. Capability of some or all of the children are limited such that they cannot be reasonably consulted, or

   ii. The research intervention or procedure(s) involved hold out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the investigation, or

   iii. The research meets the following requirements:

      - the research involves no more than minimal risk to the participants; and
      - the waiver will not adversely affect the rights and welfare of the participants; and
      - the research could not practicably be carried out if assent was required; and

- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
- When appropriate, pertinent information is provided after participation.

2. Decisionally impaired and/or incompetent adults
    a. The IRB determines whether assent is required in research involving decisionally impaired adults, and/or incompetent adults based on their condition, the research procedures to be used, and the general purpose of the research.
    b. If assent is determined appropriate in decisionally impaired adults, and/or incompetent adults, the individual should be given an explanation, at a level appropriate to the individual's condition, of the procedures to be used, their meaning in terms of discomfort and inconvenience, and the general purpose of the research.
    c. If assent is determined appropriate in decisionally impaired adults, and/or incompetent adults, documentation of assent is required. Generally, assent is documented by having the individual sign the consent form in the designated signature section.
    d. The IRB may waive its requirements for obtaining or documenting assent appropriate in decisionally impaired adults, and/or incompetent adults, if the IRB determines:
        a. the research involves no more than minimal risk to the participants; and
        b. the waiver will not adversely affect the rights and welfare of the participants; and
        c. the research could not practicably be carried out if assent was required; and
        d. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
        e. When appropriate, pertinent information is provided after participation.

B. Consent

1. Minors (Children)
    a. In accordance with 45 CFR 46.408(b) the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent, guardian, or LAR.
    b. Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(b)(1-9) and any additional elements the UTSW IRB deems necessary (see 3.1. INFORMED CONSENT REQUIREMENTS).
    c. Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research. Unless "emancipated," minors may not legally give consent. Therefore, the researchers must obtain the parent(s) or legal guardian(s) permission before enrolling a minor in the research as follows:
        i. Permission of one parent is sufficient for research involving:
            1. minimal risk (§46.404/§50.51), or
            2. more than minimal risk with the prospect of direct benefit (§46.405/§50.52).

ii. Both parent's permission is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child for research:
    1. involving greater than minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge about the subjects' disorder or condition (§46.406/§50.53), or
    2. not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (§46.407/§50.54).

    When only one parent accompanies the child to a visit, they should be asked to provide the contact information of the other parent. The investigator/study team should contact the other parent to discuss the study and to arrange to obtain consent. The child may not be enrolled until the study team has obtained consent from both parents and assent (as applicable). It is important for the investigator to document all attempts to contact the absent parent, along with the basis for any determination that they are "reasonably unavailable."

d. A minor is only "emancipated" (and therefore able to consent for him/herself) in Texas by a court order, though the proper legal terminology is that the person has had the disabilities of minority removed. If the person under age 18 is "emancipated", then the subject is treated as an adult and may provide informed consent for themselves.
e. In Texas, a minor may consent to medical, dental, psychological, and surgical treatment for him or herself, and hence may also consent to research for the same circumstances/treatment, if the minor is:
    i. is on active duty with the armed services of the United States of America;
    ii. is:
        1. 16 years of age or older, and
        2. residing separate and apart from the his/her parents, managing conservator, or guardian (with or without consent and regardless of duration), and
        3. managing his/her own financial affairs (regardless of the source of the income);
    iii. is seeking the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the licensed physician or dentist to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code;
    iv. is unmarried, pregnant and consents to hospital, medical, or surgical treatment, other than abortion, related to the pregnancy;
    v. is seeking an examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use; or
    vi. is serving a term of confinement in a facility of the Texas Department of Criminal Justice.
f. A provider may rely on the written statement of the child containing the grounds on which the child has capacity to consent to the medical treatment

g. When conducting the study, investigators may need to make decisions on a subject-by-subject basis regarding the applicable state statutory requirements. If there are questions relating to whether an individual meets the state statutory requirements to be emancipated or to give consent without an LAR, the investigator should consult the UT Southwestern legal counsel.

2. Research Involving Decisionally Impaired Subjects

   a. The federal regulations define "legally authorized representative" as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." Under Texas law, this means the consent must come either from the legal guardian of the subject, or, in the case of research that is part of medical treatment, from the subject's health care agent
   b. The PI may obtain consent by a legally authorized representative only in situations where the prospective subject is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note.
   c. The determination that a subject is incompetent or has an impaired decision-making capacity must be made by a legal determination or a determination by the practitioner (e.g., a psychiatrist or licensed psychologist may be consulted if based on mental illness diagnosis). This determination may be made independently, in consultation with another qualified individual or after appropriate medical evaluation it is determined that the prospective subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
   d. The IRB may require investigators to conduct a preliminary competency assessment whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects
   e. The investigator advises the LAR of his/her role and responsibilities in serving as the decision-maker for the subject. The investigator also advises the LAR that it is his/her obligation to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what he/she thinks is in the incompetent person's best interest.
   f. If feasible, the investigator explains the proposed research to the prospective subject even when the LAR gives consent.
   g. For subjects whose decision-making capacity may fluctuate and either regain capacity to consent or those with decreasing capacity to give consent, a re-consenting plan may be required by the IRB.

3. Obtaining Informed Consent of Children or persons with DADMC outside the State of Texas

   a. If the PI is conducting the research outside the state of Texas and the research involves children or persons with diminished autonomous decision-making capacity (DADMC) the investigator must follow the requirements of the state/country in which he/she will conduct the research to determine which individuals meet the applicable legal or regulatory definitions for child/children, LAR, or guardian.

   b. The PI should consult UTSW legal counsel when preparing the IRB application.

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS
Title 2, Texas Family Code § 31.001 - REMOVAL OF DISABILITIES OF MINORITY REQUIREMENTS
Title 2, Texas Family Code § 32.003 - CONSENT TO TREATMENT BY A CHILD
Title 4, Texas Health and Safety Code § 313.004 - CONSENT FOR MEDICAL TREATMENT

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
January 2019	HRPP	Revision to reference 2019 common rule
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures