Policy Name: Research Informed Consent by Surrogate	
Policy Owner: Research Activities and Compliance Committee	**Effective Date:** 01/30/2024
Approved By: System Performance Alignment & Innovation (SPAN)	**Last Reviewed Date:** 01/30/2024
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1.0 Scope:

1.1 Applicable Entities:
This policy applies to:
- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals
- Texas Health Physicians Group
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities (except those listed in the Formulation and Adoption of System-Wide Policies and Procedures in Section 4.1.6 or in Section 4.1.7)

1.2 Applicable Departments:
This policy applies to all departments.

1.3 Applicable Personnel:
Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record

2.0 Purpose:

2.1 This policy is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct research with children and persons who have impaired decision-making capacity and

2.2 To establish and communicate requirements for the documentation and process for obtaining informed consent by surrogate for children and adults unable to give consent who participate in research activities at Texas Health.

3.0 Policy Statements:

3.1 It is Texas Health policy that researchers may not involve a human being as a participant in research unless the investigator has obtained IRB approval for the research and, when required by the IRB, also obtains that person’s legally effective informed consent.

3.2 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 (LAR), also known as "surrogate consent."

4.0 Policy Guidance:

4.1 <u>Assent of Subjects</u>

4.1.1 In addition to the requirements outlined in the Research Informed Consent Policy, the Principal Investigator (PI) is responsible for including in the IRB application, a description of the process/procedure for obtaining and documenting assent, when research includes:

a. Minors (Children - Individuals under the age of 18 years)

b. Decisionally impaired and/or incompetent adults. Adults unable to provide consent.

4.1.2 Research Involving Minors (Children).

a. In the state of Texas, a minor is a person who is under the age of 18.

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 consider 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 consent process and, if applicable, the assent process to ensure compliance with IRB guidance and federal requirements. In general, when 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:

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

2) 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.

3) 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 considered 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, then 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:

1) The capability of some or all of the children are limited in a manner such that they cannot be reasonably consulted, or

2) 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

3) The research meets the following requirements:

i. the research involves no more than minimal risk to the participants; and

ii. the waiver will not adversely affect the rights and welfare of the participants; and

iii. the research could not practicably be carried out if assent was required; and

iv. 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

v. when appropriate, pertinent information is provided after participation.

4.1.3 Research Involving Decsionally Impaired and/or Incompetent Adults.

a. The IRB will determine 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:

1) the research involves no more than minimal risk to the participants; and

2) the waiver will not adversely affect the rights and welfare of the participants; and

3) the research could not practicably be carried out if assent was required; and

4) 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

5) when appropriate, pertinent information is provided after participation

4.2 Informed Consent of Subjects via Surrogate

4.2.1 In addition to the requirements outlined in the Research Informed Consent Policy, the Principal Investigator (PI) is responsible for including in the IRB application, a description of the process/procedure for obtaining and documenting consent, when research includes minors (children) and decisionally impaired and/or incompetent adults (adults unable to provide consent).

4.2.2 Research Involving Minors

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 Legally Authorized Representative (LAR).

b. Parents or guardians must be provided with the basic elements of consent as stated in Federal Regulation 45 CFR 46.116(b)(1-9) and including any additional elements the IRB deems necessary.

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, researchers must obtain the parent(s) or legal guardian(s) permission before enrolling a minor in the research as follows:

1) Permission of one parent is sufficient for research involving minimal risk or more than minimal risk with the prospect of direct benefit

2) 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 involving greater than minimal risk with no prospect of direct benefit but likely to yield generalizable knowledge about the subjects' disorder or condition or not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

3) 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/herself, and hence may also consent to research for the same circumstances/treatment, if the minor is:

1) on active duty with the armed services of the United States of America; or

2) 16 years of age or older, and residing separate and apart from his/her parents, managing conservator, or guardian (with or without consent and regardless of duration), and also managing his/her own financial affairs (regardless of the source of the income); or

3) 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, Texas Health and Safety Code; or

4) unmarried, pregnant and consents to hospital, medical, or surgical treatment, other than abortion, related to the pregnancy; or

5) 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

6) 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 THR legal counsel.

4.2.3 Research Involving Decisionally Impaired and/or Incompetent Adults.

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.

5.0 Definitions:

5.1 A Minor - In the state of Texas is a person who is under the age of 18.

5.2 Assent - Means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

5.3 Decisionally Impaired/Incompetent Persons - Are those who have a diminished capacity to understand the risks and benefits for participation in research and to autonomously provide informed consent.

5.4 Guardian - Means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

5.5 Legally Authorized Representative (LAR) - Means 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.

5.6 Permission - Means the agreement of parent(s) or guardian to the participation of their child or ward in research.

6.0 Responsible Parties:

6.1 Texas Health Research Activities and Compliance Committee (RACC)

6.1.1 Has responsibility for the oversight and implementation of this policy.

7.0 External References:

7.1 "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

7.2 Department of Health and Human Services (DHHS) Regulations. 45 CFR Part 46, subpart A 45 CFR Part 46 Subpart A

7.3 The DHHS human subject regulations (Subpart B); (Subpart C); and (Subpart D).

7.4 FDA regulations 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 50, Subpart D, 21 CFR Part 312, 21 CFR Part 600, and 21 CFR Part 812.

7.5 HIPAA regulations 45 CFR 164.501, 164.508, 164.512(i).

7.6 Title 2, Texas Family Code § 31.001 - REMOVAL OF DISABILITIES OF MINORITY REQUIREMENTS https://statutes.capitol.texas.gov/Docs/FA/htm/FA.32.htm

7.7 Title 2, Texas Family Code § 32.003 - CONSENT TO TREATMENT BY A CHILD

7.8 Title 4, Texas Health and Safety Code § 313.004 - CONSENT FOR MEDICAL TREATMENT

8.0 Related Documentation and/or Attachments:

8.1 Research Informed Consent - THR System Policy

8.2 Research Engagement - THR System Policy

8.3 Human Research Protection Program - THR System Policy

8.4 Research Principal Investigator Obligations - THR System Policy

8.5 Record Retention - THR System Policy

8.6 Research Record Retention - THR System Policy

8.7 Research Privacy - THR System Policy

9.0 Required Statements:

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.