# IRB Form # 2D

**Application for Research Including Children as Research Subjects**

**Principal Investigator:**

**Protocol # and Title:**

This form should be submitted in conjunction with IRB Form #1 when children (0-17 years of age) are used as human subjects in a research protocol.

The following questions will assist the IRB in determining that the research fulfills all the requirements of the UTA IRB SOPs and applicable federal regulations for inclusion of children as research subjects.

# Definitions:

Children – Persons who have not attained the legal age for consent to treatment or procedures involved in the research investigations under the applicable laws of the jurisdiction in which the research will be conducted.

Minimal Risk Research - Research in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life (of normal subjects) or during the performance of routine physical or psychological examinations or tests.

Assent – A child’s affirmative agreement to participate in the research investigation. Mere failure to object should not, absent affirmative agreement, be construed as assent. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Consent/Permission – The agreement of the parent(s) or guardian to the participation of their child.

Parent – A child’s biological or adoptive parent.

Guardian – An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes research investigations.

# For Completion by the Principal Investigator:

The IRB’s first determination is whether or not the research is minimal risk or greater than minimal risk. The second determination is whether or not there is a prospect for direct benefit to the individual subjects. Based on this information, the IRB will determine parental permission and assent requirements.

According to the definition given above, is the proposed research investigation **greater than minimal risk**?

**Yes** If yes, complete **only Section A.**

**No** If no, complete **only Section B.**

Will wards/foster children be included in the research?

**Yes**

**No**

**SECTION A: Please complete this section only if your research is GREATER than minimal risk.**

*Benefits are considered to be from* ***the actual research****, not as compensation from the investigators (i.e. payment for participating).*

Does your research present the prospect of ***direct benefit to the individual subject***?

**Yes** If yes, complete **Part 1** of this section.

**No** If no, complete **Part 2** of this section.

# PART 1:

## 45 CFR 46.405 or 21 CFR 50.52: Research investigation involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

1) Are the risks justified by the anticipated benefits?

2) Is the relationship of the anticipated benefit to risk at least as favorable as alternative approaches?

3) How will the assent of children be obtained? Are all children capable of providing assent?

4) How will the parental permission of the parent(s) or guardian(s) be obtained and documented?

*The IRB may determine that the permission of one or both parents is required for research in this category, and will determine whether assent for some or all minors is required.*

# PART 2:

## 45 CFR 46.406 or 21 CFR 50.53: Research investigation involving greater than minimal risk with no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subjects’ disorder or condition.

1) Does the risk represent a minor increase over minimal risk?

2) Does the intervention or procedure present experiences commensurate with those inherent in the subjects’ actual or expected medical, dental, psychological, social or educational experience? Please explain.

3) Is the intervention or procedure likely to yield generalizable knowledge about the subjects’ disorder or condition that is vital to understanding or ameliorating the subjects’ disorder or condition? Please explain.

4) How will the assent of children be obtained? Are all children capable of providing assent?

5) How will the informed consent of the parents or guardians be obtained and documented?

*The permission of both parents is required for research in this category, unless one parent cannot reasonably provide permission, as allowed per Subpart D. The assent of the minors involved is required unless the Board determines that some or all are not capable of providing assent.*

**SECTION B: Please complete this section only if your research is NOT greater than minimal risk.**

**45 CFR 46.404 or 21 CFR 50.51: Research or clinical investigation not involving greater than minimal risk.**

1. How will the assent of children be obtained? Are all children capable of providing assent?
2. Will permission of the parent(s) or guardian(s) be obtained and documented? If not, please fill out a [request for a waiver of informed consent](https://resources.uta.edu/research/regulatory-services/human-subjects/irb-forms-and-templates.php).

*If consent cannot be waived in accordance with 45 CFR 46.116(d), the IRB, or designated expedited reviewer, will almost always require that the permission of only one parent is necessary for research in this category, and will determine whether assent is required for some or all minors. However, the IRB has the discretion to require that the permission of both parents must be obtained*.