



THE UNIVERSITY OF TEXAS AT ARLINGTON

IRB Form # 2D Application for Research Including Children as Research Subjects

Principal Investigator: _____

Protocol 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 federal regulations at 45 CFR Part 46, Subpart D and 21 CFR Parts 50 and 56 for inclusion of children as research subjects. Special risk/benefit determinations must be discussed and documented by the IRB in order for children to be included as research subjects. Exemptions from the regulations of human subjects involved in research do not apply for children subjects *except* during research that is strictly observation of public behavior and the Principal Investigator does not participate in the activities being observed. If you believe your research to be exempt, please complete and submit IRB Form # 1A (in lieu of IRB Form #1) along with this application for research including 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.

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 more than minimal risk. The second determination is whether or not there is a prospect for direct subject benefit. The IRB may approve the inclusion of children in research investigation activities only after making determinations specified in the appropriate sections of 45 CFR Part 46, Subpart D or 21 CFR Parts 50 and 56.

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

YES If yes, complete only Section A and the Signature Portion.

NO If no, complete only Section B and the Signature Portion.

SECTION A: Please complete this section only if your research is MORE 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 more than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

Determination:

1) Are the risks justified by the anticipated benefits?

YES NO

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

YES NO

3) Are adequate provisions made for obtaining assent of the children?

YES NO

4) Will the informed consent of the parent(s) or guardian(s) be obtained?

YES NO

In order to approve the research/clinical investigation under this category, questions 1- 4 above must be answered "YES."

PART 2:

45 CFR 46.406 or 21 CFR 50.53: Research investigation involving more 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.

Determination:

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

YES NO

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?

YES NO

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?

YES NO

4) Are adequate provisions made for obtaining assent of the children?

YES NO

5) Will the informed consent of the parent(s) or guardian(s) be obtained?

YES NO

In order to approve the research/clinical investigation under this category, questions 1 - 5 above must be answered "YES."

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

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

Determination:

- 1) Are adequate provisions made for obtaining assent of the children? Verbal assent should be given to children 5 - 6 years of age while written assent should be given to children from 7 - 17 years of age.

YES NO

- 2) Will the informed consent of the parent(s) or guardian(s) be obtained?

YES NO

In order to approve the research investigation under this category, both 1 and 2 above must be answered "YES."

SIGNATURE PORTION:

I UNDERSTAND THAT I AM RESPONSIBLE FOR THE ACCURACY OF THE STATEMENTS MADE IN THIS FORM AND FOR THE CONDUCT OF RESEARCH INVOLVING CHILDREN AS SUBJECTS.

Principal Investigator

Date

Faculty Sponsor (If not the Principal Investigator)

Date

Please submit this form with your corresponding IRB paperwork to the Office of Research Compliance, Box 19188. If you have any questions, please contact the Office of Research Compliance at 817-272-3723, or see Research Compliance at: <http://www.uta.edu/ra/>.