University of Toledo
Social, Behavioral and Educational IRB
Information for Research Involving Children as Research Subjects[1]

There are special requirements for research involving children that are found in Subpart D of the HHS regulations for the protection of human subjects in research. These regulations provide additional protection for research participants who are under 18 years of age. All University of Toledo Related Research[2] that involves individuals less than 18 years of age must apply these protections. If a research participant reaches 18 years of age while the research is ongoing (including data analysis), the participant must be re-consented under the standard adult informed consent process. The purpose of this document is to highlight the requirements of Subpart D.

Definitions – Federal Regulations 45 CFR 46.402

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

"Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Ohio, legal age for consent is eighteen years old.

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

"Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

"Parent" means a child's biological or adoptive parent.

Investigator Responsibilities When Conducting Human Research Involving Children

Investigators involving children in research must comply with the requirements in Subpart D, as well as the Common Rule/Subpart A, other applicable subparts (e.g. Subpart B for pregnant participants and Subpart C for incarcerated participants), and University of Toledo DHRP Policies and Procedures.

- Obtain permission of one or both parents, based on federal requirements. Permission must be documented with the parent(s) signature on a written permission form that contains all elements of the standard adult informed consent form.
- Obtain the assent of the child. Document the assent, and obtain written signed assent when required by the IRB (generally a signature is required for older children).
- Understand the categories of research involving children that an IRB may approve.

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[1] Biomedical research involving children is reviewed by the St. Vincent Mercy Medical Center's Pediatric IRB pursuant to a written IRB agreement. The Pediatric IRB has the required expertise to review biomedical research involving children. A representative from UT serves as a community member on the Pediatric IRB.

[2] Defined in the UT DHRP Policies and Procedures – ***UT Related Research*** means research carried out on- or off-campus (including other states or countries) by UT faculty, students, or other employees, and any studies conducted by any investigator using UT facilities and/or UTMC patients as subjects, including patient records, biological samples, or surveys.

Institutional Review Board Responsibilities

In addition to other responsibilities assigned to the IRB under federal regulations and University policies, the IRB shall only approve research that satisfies the additional protections for child research participants. **[§ 46.403 IRB duties; UT DHRP Policy]**

- Requiring IRB review of some research activities involving children that would be exempt if research subjects were adults (e.g. observation with investigator participation, surveys or interviews).
- Require parental permission and child assent [46.408] instead of the usual informed consent process used for adults.
- The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. The IRB shall take into account the ages, maturity, and psychological state of the children involved.
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