PROTECTION OF CHILDREN INVOLVED IN RESEARCH

Under this policy, children include all those who have not yet reached their 18th birthday (i.e., 0 through 17 years old).

The special vulnerability of children makes consideration of involving them as research subjects particularly important.

To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research that involves children.

Exceptions to the “17 year old” rule depend on the jurisdiction in which the research will take place. In Texas, the following are considered adults and thus are not children (Title 4, Tex. Health & Safety Code § 313.002(1); Title 6, Tex. Civ. Practice & Remedies Code § 129.001). A minor can have the disabilities of minority removed by a legal proceeding under Title 2, Tex. Family Code § 31.001:

(1) one who is 18 years of age or older; or
(2) someone under age 18 who has had the disabilities of minority removed by court order (what is commonly referred to as being “emancipated” though that word is not used in the statute). [Note: If there is a question as to whether a potential participant is emancipated or whether the removal of disabilities was limited and does not include health care decision-making, the researcher should read the actual court order.]

The IRB and researchers must be familiar with Texas and other relevant state laws regarding emancipation and other criteria that affect consent procedures for individuals under the age of 18 years.

The policies in this document are derived from: http://www.hhs.gov/ohrp/children/.

To What Do These Regulations Apply?

a. This policy applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services and/or The University of Texas at Tyler.

• This includes research conducted by Department/UT Tyler employees, except that each head of an Operating Division of the Department may adopt such non-substantive, procedural modifications as may be appropriate from an administrative standpoint.
• It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of §46.101 of subpart A (see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101), waive the applicability of some or all of the requirements of these regulations for research of this type.

b. Exemptions to this policy include [taken from 46.101(b)(1) and (b)(3) through(b)(6)], and partial exemption to (b)(2) are listed below. However, only the IRB must make final determination as to any exemptions that may be covered.

• Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

• Research involving survey or interview procedures or observations of public behavior does not apply to research covered by this policy except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

• Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if the federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

• Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

• Research and demonstration projects which are conducted by or subject to the approval of department or agency heads and which are designed to study, evaluate, or otherwise examine:
  (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives
to those programs or procedures; or (iv) possible changes in methods or
levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies (i) if
  wholesome foods without additives are consumed or (ii) if a food is
  consumed that contains a food ingredient at or below the level and for a
  use found to be safe, or agricultural chemical or environmental
  contaminant at or below the level found to be safe by the Food and Drug
  Administration or approved by the Environmental Protection Agency or the
  Food Safety and Inspection Service of the U.S. Department of Agriculture.

c. The exceptions, additions, and provisions for waiver as they appear in
paragraphs (c) through (i) of §46.101 of subpart A (see:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cf46.htm#46.101)
are applicable to this policy.

II. Definitions

The definitions in §46.102 of subpart A (see:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cf46.htm#46.102) shall be
applicable to this policy as well. In addition, as used in this policy:

- **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.
- **Assent** means a child’s affirmative agreement to participate in research.
  Mere failure to object should not, absent affirmative agreement, be
  construed as assent.
- **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.
- **Guardian** means an individual who is authorized under applicable State or
  local law to consent on behalf of a child to general medical care.

III. UT Tyler IRB Duties

In addition to other responsibilities assigned to the UT Tyler IRB under this part,
the UT Tyler IRB shall review research covered by this policy and approve only
research which satisfies the conditions of all applicable sections of this policy.

Expert consultants shall be part of the review process for all categories except
“a”.

a. Research not involving greater than minimal risk
HHS/UT Tyler will conduct or fund research in which the UT Tyler IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408. Therefore, no research proposals using children as subjects will be considered as exempt from IRB review.

b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects

HHS/UT Tyler will conduct or fund research in which the UT Tyler IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

1. The risk is justified by the anticipated benefit to the subjects;

2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408

c. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition

HHS/UT Tyler will conduct or fund research in which the UT Tyler IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

1. The risk represents a minor increase over minimal risk;

2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
4. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

d. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

HHS/UT Tyler will conduct or fund research that the IRB does not believe meets the requirements of Sections (a), (b), or (c) only if:

(a) The UT Tyler IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; 

(b) The DHHS Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

• That the research in fact satisfies the conditions of Sections (IIIa), (IIIb), or (IIIc ), as applicable, or
• The following:

  (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

  (ii) The research will be conducted in accordance with sound ethical principles;

  (iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in Section IV.

IV. Consent and Assent: Requirements For Permission By Parents Or Guardians And For Assent By Children

A. Adequate Provisions for Child’s Assent

The UT Tyler IRB must make adequate provisions for soliciting the assent of child subjects when the children are capable of providing assent. In determining whether children are capable of assenting, the IRB should 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. The child should be given an explanation of
the proposed research procedures in a language that is appropriate to the child’s age, experience, maturity, and condition.

B. Age Requirements for Assent

Due to variations in child development maturity levels, these are to serve as guidelines only.

- For children 6 years of age and under: No actions, parental consent only.
- For children 7-12 years of age: Child must be able to provide verbal agreement in addition to parental consent; if child verbally disagrees, no coercion must take place by parent or other.
- For children 13-17 years of age: Written assent by child and written consent by parent required.

Researchers must justify their decision as to whether or not to obtain children’s assent.

When assent is obtained, documentation must reflect the manner in which it was obtained.

C. Waiver of Assent

If the UT Tyler IRB determines any of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:

a) the capability of some or all of the children is so limited that they cannot reasonably be consulted, or

b) when the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

c) in such circumstances a child's dissent, which should normally be respected, may be overruled by the child's parents, at the discretion of the UT Tyler IRB. Even where the UT Tyler IRB determines that the child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for adults, as is reflected in §46.116.

D. Adequate Provisions for Parent or Guardian Permission

The investigator must make adequate provisions for soliciting the permission of each child’s parents or legally authorized representative.

Some circumstances exist that only one parent’s permission is needed and others where both, except under special circumstances described below, signatures would be required.
a) Permission of one parent is sufficient for research to be conducted under either of the following circumstances, as is reflected in §46.404, §46.405, and §46.407

i. §46.404: Research not involving greater than minimal risk

Minimal risk means that 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 or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

ii. §46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (§46.405) when the IRB finds that the intervention or procedure holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, and if the UT Tyler IRB determines that:

a) the risk is justified by the anticipated benefit to the subjects,

b) that the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches,

c) that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

b) Permission is to be obtained from both parents 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, under the two following circumstances that reflect §46.406 and §46.407:

i. §46.406: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

When the research involves greater than minimal risk to children and involves an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject
Additionally, the UT Tyler IRB must find that:

i) the risk represents a minor increase over minimal risk
ii) that the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
iii) that the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, and
iv) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

ii. §46.407: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

When the UT Tyler IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and the Secretary of the Department of Health and Human Services approves the research, and permission is to be obtained from parents, both parents must give their permission 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.

E. Waiver of Parental or Guardian Permission

If parental or legally authorized representative permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), the investigator may request that the UT Tyler IRB waive the consent requirements described above, provided both an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with Federal, State, or local law. 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.

F. Documentation

Permission by parents or guardians shall be documented in the same manner as required for other subjects. When the UT Tyler IRB determines that assent of a child is required, it shall also determine whether and how assent must be documented.
V. Wards

For research involving wards of the state of Texas, “ward” includes foster children ((Title 5, Tex. Family Code, §266.001(2), (4)), children residing at a Texas Youth Commission facility (Title 3, Human Resources Code, §§ 63.001-63.028) and children who are otherwise in the care and control of the state or a state agency.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under Section III(c) and Section III(d) of this policy only if such research is:

- Related to their status as wards; or
- Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this Section, the UT Tyler IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.