

THE IRB REVIEW

Volume 3, Number 4

December 2007

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Studies Involving Children As Participants

The ETSU and ETSU/VA IRB will consider certain groups of human subjects to be particularly vulnerable to coercion or undue influence in a research setting. In reviewing research projects, the IRB will scrutinize those involving these vulnerable groups, to ascertain that their use is adequately justified, and additional safeguards are implemented to minimize risks unique to each group. This newsletter will explain the requirements and process of a study that involves children as participants. The State of Tennessee states that anyone under the age of 18 is a minor. The VA may not involve children in studies.

The IRB, when reviewing research involving children as participants, considers the risks, benefits, and discomforts in the proposed research and assesses their justification in light of the expected benefits. When assessing the risks and benefits, the IRB weighs the circumstances of

the children under study, the magnitude of risks that may accrue from the research, and the potential benefits to the child or to society. The assessment of the probability and magnitude of the risk may be different in sick children and may vary depending on the disease the child may have. When assessing possible benefits, the IRB must also consider the variability in health statuses, taking into account the current health status and the likelihood of progression to a worsened state without the research intervention.

Federal regulations require the IRB to classify research involving children into one of the four categories and to document discussion of the risks and benefits of the research study. For a detailed list of the categories, go to the [December 2005 newsletter](#) or [IRB Policy 15](#) on the IRB website.



Children as Participants

In all cases, the IRB must determine that adequate provisions have been made for soliciting the assent of children and permission of parents or guardians.

Supplemental Forms

In order for the IRB to make the appropriate determinations, the IRB requires that Principal Investigators involving children in their studies complete a Supplemental Form for Studies with Children participants (available on our website) along with the other required documents at the time of submission. This form requires the evaluation of

the risk/ benefits according to the Principal Investigator, an assessment of whether the study involves Wards of the State, a description of how the permission of parents or guardians will be sought and a description of how the assent of the child will be sought. This form along with the other submitted documents will be sent to the

child advocate, chosen by the IRB Chair or Vice-Chair, who will evaluate the study.





Why does the IRB Require these determinations about Children?

ETSU commits to comply with the requirements set forth under 45 CFR 46, as well as the terms of assurance under the Federal Wide Assurance (FWA) accepted and approved by the Department of Health and Human Services (DHHS) no matter the source of funding.

It is the policy of East Tennessee State University (ETSU) and the James H. Quillen Veterans Affairs Medical Center (VAMC) at Mountain Home

(Johnson City), Tennessee to comply with all applicable local, state, federal, and international regulations in the conduct of human subject research. Written procedures are required to document the management of assurance of compliance. In accordance with the Federal Policy on the Protection of Human Subjects (DHHS) Title 45, Code of Federal Regulations (CFR), part 46, Food and Drug Administration (FDA) Title 21 CFR Parts 50 and 56, 38 CFR 16), ETSU and VAMC are jointly responsible for the

protection of the rights and welfare of human subjects of research conducted by, or under the supervision of physicians, faculty, staff, or students.

The IRB requires that when conducting a study that involves children as participants, the PI must solicit the permission of the parent or guardian unless waived.



Soliciting Permission from the Parent or Guardian

45 CFR 46.408(b) states, "In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by [§46.116](#) of [Subpart A](#), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under [§46.404](#) or [§46.405](#). Where research is covered by [§§46.406](#) and [46.407](#) 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."

The IRB shall require the permission of each child's parents or guardian. Only parents may grant permission for their child's participation in research. Assent is sought from the child only after permission has been obtained from the parent(s). Grandparents and other relatives may not grant permission unless they have been granted formal custody of the child by a court. In such cases, the PI must obtain a copy of the court order as evidence of that person's authority.

is to be obtained from the 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.

When parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405 (categories 1 and 2). For research covered by 45 CFR 46.406 and 45 CFR 46.407, (greater than minimal risk and no direct benefit or otherwise unapprovable) and permission

Soliciting the Assent of the Child Involved

45 Cfr 46.408(a) states, "In addition to the determinations required under other applicable sections of this subpart, 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. In determining whether children are capable of assenting, the IRB shall 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, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds 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 research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#).

Regulations require that the IRB determine that adequate provisions are made for obtaining and documenting the assent of the children, when in the judgment of the IRB, the children are capa-

ble of providing assent. In determining whether children are capable of assent, the IRB shall take into account the age, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in the research under a particular protocol, or for each child, as the IRB deems appropriate. When the IRB determines that assent is required, it will also determine whether and how assent must be documented. See sample assent on page 4.



Obtaining assent of the child

The IRB requires that when conducting a study that involves children as participants, the PI must obtain assent unless waived

Wards of the State

Children who are wards of the State or other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 45.407 only if such research is either:

- 1) related to their status as wards or
- 2) be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

In research approved under 45

CFR 46.406 or 45 CFR 46.407, the IRB must require appointment of an advocate for each child who is a ward. This advocate serves in addition to any other individual acting on behalf of the child as a guardian or 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 guardian organization. The IRB documents determinations regarding children as wards.



Wards of the State

Sample Assent

In addition to the determinations required under other applicable sections of this subpart, 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. In determining whether children are capable of assenting, the IRB shall 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, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds 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 research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#).

This sample assent may be used for children participants ages 7-13. This is **not** a required template. However, this may help anyone involving children in studies to understand what may be required on the assent by the IRB. You are welcome to do your own template as long as the information on this sample is included.

ETSU and ETSU/VA IRB Sample Assent Document for Research Study

PI:

Title of Study:

Name of Participant _____ Age _____

Here are answers to some questions that you may have. Please ask any questions that you have about what is written on this page. Also ask any other questions that you have about this research. You will be given a copy of this assent form.

1. Why are you doing this research?
2. What will I do if I am in this research?
3. How long will it take?
4. Can this research help me or other people?
5. Can bad things happen to me in this research?
6. Do I have to be in this research study and can I stop if I want to?
7. Who will know that I am in this research?
8. Can I do something else instead of this research?
9. Who do I talk to if I have questions?

Signature of Participant

Date

**THE OFFICE FOR
THE PROTECTION
OF HUMAN
RESEARCH
SUBJECTS**

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We're on the web

December 2007

Sun	Mon	Tue	Wed	Thu	Fri	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

4-Medical Meeting
6- Campus Meeting
10- Deadline to submit initial full studies for the January 2008 meeting
25-Jan 1- Christmas holiday (ETSU CLOSED)

January 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

3-Campus Meeting
8- Medical Meeting
14- Deadline to submit initial full studies for the February 2008 meeting
14- Spring Semester Starts
21- ETSU CLOSED

Waiver of Assent

The IRB may waive the requirement for assent of some or all of the children when:

- ⇒ The capability of some or all of the children is so limited that they cannot reasonably be consulted **or**
- ⇒ The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research

Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:

- ⇒ The research involves no more than minimal risk to the participants;
- ⇒ The waiver will not adversely affect the rights and welfare of the participants;
- ⇒ The research could not practicably be carried out without the waiver; and
- ⇒ Whenever appropriate, the participants will be provided with additional pertinent information after the participation.