



RESEARCH INVOLVING MINORS WHO ARE WARDS OF THE STATE

2/19/2016

The Duke University Health System (DUHS) Institutional Review Board (IRB) has adopted the following policy governing the review of research at DUHS involving minors who are Wards of the State.

For the purposes of this document, a “Ward” or “Ward of the State” shall mean a minor (under 18 years of age) who is under the legal custody of the State or any other agency, institution, or entity (e.g., a minor placed in foster care in accordance with applicable state law).

Determination of Risk Level

The DUHS IRB will be guided in its review of research involving Wards of the State by the requirements of 45 CFR 46 Subpart D and 21 CFR 50 Subpart D. The DUHS IRB will, in the course of its review, make an independent determination of the risk level of such research as defined in 45 CFR 46.404-407 or 21 CFR 50.51-54 and as described in the policy entitled “Research Involving Children.”

In addition, the DUHS IRB will be guided by the requirements for permission by the guardian and, if applicable, assent by the Ward as described in 45 CFR 46.408 or 21 CFR 50.55. The *guardian* is defined as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care [45 CFR 46.402(e), 21 CFR 50.3(s)]. Under North Carolina law, a guardian of a child must be appointed by a court under Article 6 of Chapter 35A of the North Carolina General Statutes.

I. Research not involving greater than minimal risk

Research involving Wards that meets the requirements of 45 CFR 46.404 or 21 CFR 50.51 will be reviewed by the DUHS IRB according to the regulations using the expedited procedure as described in 45 CFR 46.110, 21 CFR 56.110 and 64 FR60364-60367, November 9, 1998.

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

Research involving Wards that meets the requirements of 45 CFR 46.405 or 21 CFR 50.52 will be reviewed by a convened IRB which will consider the appropriateness of the participation of Wards in the study. The IRB’s review of this aspect of the study will be documented in the minutes of the meeting.

III. 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, or research not otherwise approvable

When the risk level is determined to meet the criteria described in 45 CFR 46.406-407 or 21 CFR 50.53-54, Wards will only be permitted to participate in research if the DUHS IRB determines that the research study satisfies the two criteria described in 45CFR46.409(a) or 21 CFR 50.56(a) as indicated on the attached form (Attachment I).

Appointment of an Advocate

In the course of its review of this research, the convened IRB will require appointment of an advocate for the Ward¹ who will fulfill the requirements of 45 CFR 46.409(b) or 21 CFR 50.56(b). The appointment of the advocate will be in addition to any other individual acting on behalf of the Ward as guardian or in loco parentis. This advocate will issue a statement to the DUHS IRB substantially the same as the statement in Attachment II.

The advocate shall be an individual who has the appropriate background and experience to act in, and agrees to act in, the best interest of the Ward for the duration of the child's participation in the clinical investigation. Examples of appropriate expertise include, but are not limited to, education/experience in pediatric medicine, law, child advocacy, foster parenting, behavioral sciences and child psychology.

The advocate shall be an individual 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.

In the event that an individual is no longer able to serve as an advocate, he/she will immediately notify the DUHS IRB in writing. The DUHS IRB will promptly nominate and appoint a new advocate for the research study.

Any amendments to a study involving Wards that require review by a convened IRB will be reviewed only in the presence of the advocate(s).

Requirement of FDA and/or DHHS Approval

In addition to the review described above, research involving Wards that meets the requirements of 45 CFR 46.407 will obtain the approval of the Secretary of Health and Human Services after review by a convened IRB and prior to issuance of a Notification of Approval. Research involving Wards that meets the requirements of 21 CFR 50.54 will obtain approval of the Commissioner of the Food and Drug Administration after review by a convened IRB and prior to issuance of a Notification of Approval.

¹As provided by 45 CFR 46.409(b) and 21 CFR 50.56(b)(2), one individual may serve as advocate for more than one Ward.

ATTACHMENT I

(For use with a research study having a pediatric risk level described in 45 CFR 46.406-407.)

I. Study Information

IRB Registry #

Study Title:

Principal Investigator:

The research study cited above has been determined by a convened IRB to:
 present a risk to participants that is a minor increase over minimal with no prospect of direct benefit (45 CFR 46.406 or 21 CFR 50.53)
 constitute research that is not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407 or 21 CFR 50.54)

Is inclusion of Wards necessary to complete the research? Yes No
Would exclusion of Wards adversely affect the rights and welfare of the Wards?
 Yes No

II. Requirements of 45 CFR 46.409(a) or 21 CFR 56(a)

- Is the research related to the child's status as a Ward? Yes No
- Is the research conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not Wards?
 Yes No

(Note: If no to both questions above, Wards may not participate in this study. If yes to either or both questions above, please proceed to the next section.)

III. Requirements of 45 CFR 46.409(b) or 21 CFR 50.56(b)

Name of Advocate:

Please attach the resume and/or list below the qualifications that make this individual an appropriate candidate to serve as an advocate.

Please indicate for whom this candidate would serve as an advocate:

- All minor Wards of the State in this study
- A subset of minor Wards of the State in this study
Please describe this subset:
- An individual minor Ward of the State in this study
Please describe this individual:

IV. Advocate Statement – See Attachment II

Please attach a statement from this candidate that is substantially the same as the statement in Attachment II.

STATEMENT OF APPROVAL

The nomination of [insert name of advocate] to serve as an advocate for Ward(s) on IRB # _____ has been reviewed by a convened IRB on _____ and:

____ Approved
____ Disapproved

[insert name of advocate] will serve as an advocate for the Ward(s) described below:

This appointment is in effect for the duration of the Ward(s) participation in this study unless the advocate notifies the DUHS IRB in writing that he/she is no longer able to serve as an advocate.

This appointment has been approved with the following requirements:

The advocate will:

- (i) be present at all reviews, including annual reviews, conducted by a convened IRB concerning this study;
- (ii) review the plans for obtaining assent from the Ward(s) and permission from the appropriate guardian(s)
- (iii) be present for the consent process for the Ward(s)
- (iv) receive reports, at intervals determined by the convened IRB, from the Principal Investigator on the progress of the participation of the Ward(s) in the study.

DUHS IRB Chair/Vice Chair/Designee

Date

ATTACHMENT II ADVOCATE STATEMENT

“I agree to act as an advocate for [insert description of Ward] as subjects in the research study entitled:

[insert study title] IRB [insert #]

I confirm that I will serve as an advocate for the Ward(s) described above and will review the research study with the best interests of the Ward(s) in mind. I will serve as an advocate for the duration of the Ward(s)' participation in this research study. I also confirm that, to the best of my knowledge, I have no relationship, financial or otherwise, with the research study, external sponsor, Principal Investigator, Key Personnel, or the guardian institution.

I agree to:

- (i) be present at all reviews subsequent to my appointment, including annual reviews, conducted by a convened IRB concerning this study;
- (ii) review the plans for obtaining assent from the Ward(s) and permission from the appropriate guardian(s)
- (iii) be present for the consent process for the Ward(s)
- (iv) receive reports, at intervals determined by the convened IRB, from the Principal Investigator on the progress of the participation of the Ward(s) in the study.

I will immediately notify the DUHS IRB in writing if I become unable to continue serving as an advocate.”

Advocate:

Name:

Date: