

## Rush University Medical Center Policies and Procedures

Policy Number:	RA-IRB-206
Category Name:	Research
Title:	Research Involving Children (Minors)
Type:	Policy and Procedure
Revised:	6/2009

Applies To: Rush Investigators/Study Staff, Rush IRB Members and Rush IRB Administrative Staff.

**Policy:** **Federal regulations found at 45 CFR 46, Subpart D and 21 CFR 50, Subpart D) include additional protections for children (or “minors”) involved as subjects in research. The Rush IRB approves research involving children only if this research complies with the safeguards described in these regulations, as well as this policy and procedure.**

Definitions: **Assent:** A child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

**Guardian:** An individual authorized under applicable State or local law to consent on behalf of a child to general medical care.

**Minors:** Persons who have not attained the legal age for consent to treatment or procedures involved in the research under Illinois state law. Under this policy, “minors” may be referred to as “children”.

**Parent:** Defined as a child’s biological or adoptive parent.

Procedure: Federal regulations require IRBs to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the research study in the IRB minutes. The four categories of research involving children, based on degree of risk and

benefit to individual subjects, are:

45 CFR 46.404 21 CFR 50. 51	Research (clinical investigation) not involving greater than minimal risk.
45 CFR 46.405 21 CFR 50.52	Research (clinical investigation) involving greater than minimal risk, but presenting the prospect of direct benefit to individual subjects.
45 CFR 46.406 21 CFR 50.53	Research (clinical investigation) 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.
45 CFR 46.407 21 CFR 50.54	Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

### **Parental Permissions/Consent**

Federal regulations at 45 CFR 46.408 and 21 CFR 50.55 require that the consent of the parent(s) or guardian(s) be obtained when children are being asked to participate in a research study. The consent of the parent(s)/guardian(s) must be documented in accordance with requirements set forth under 45 CFR 46.117 and/or 21 CFR 50.27, depending on the nature of the research. When research falls under 45 CFR 46.406, 46.407 or 21 CFR 50.53, 50.54, permission must be obtained from both parents unless one parent is deceased, unknown, incompetent or when only one parent has legal responsibility for the care and custody of the child.

### **Consent Exceptions**

In addition to the provisions for waiver of informed consent found at 45 CFR 46.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the

research is substituted, and provided further that 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.

### **Assent**

The Rush 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 as set forth by 45 CFR 46.408 and 21 CFR 50.55.

Children who are developmentally between the ages of 7 and 12 are generally considered capable of providing assent on a separate assent document that is written in simple language directed toward children in this age range.

Children who are developmentally over the age of 12 are generally considered capable of indicating their assent on the consent document, as the consent document should be written in language understandable to subjects with a 6<sup>th</sup> to 8<sup>th</sup> grade reading level.

The IRB may allow researchers to obtain the assent of children under the age of 12 as part of the consent document; however it is the responsibility of the Investigator to include a statement in the study application justifying the choice not to use a separate assent document when enrolling children in the study.

In determining whether children are capable of assenting, the IRB shall take into account the clinical judgment of the Investigator regarding the ages, maturity, and psychological state of the children involved. The IRB will also take into account cases where the child is too ill or too young to give assent (under 7 years of age). The IRB's decision may apply to all children involved in the research under a particular protocol, or on a case by case basis for each child, as the IRB and Investigator deem appropriate.

### **Assent Exceptions**

As outlined in 21 CFR 50.55, a child need not assent for proceeding with a clinical investigation (study) if the IRB determines that:

- a) The capability of some or all of the children is limited

- such that they could not reasonably be consulted; or
- b) The intervention or procedure involved in the clinical investigation 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 clinical investigation.

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 accordance with 45 CFR 46.116.

The Rush IRB follows RUMC Policy #OP-0029 that allows for consent, rather than assent, for legally emancipated minors 16 years or older, minors who are married, and minors who are pregnant or are parents. Minor subjects who are pregnant or are parents can also consent to the participation of their fetus/child in research.

### **Consenting minors once 18 years of age or emancipated**

When a child reaches the age of legality (18 in the state of Illinois) or becomes emancipated (see above), the consent provided by the minor's parent(s) or legal representative is no longer valid for continued participation.

Failure to re-consent minors who become of age would be akin to withholding from the subjects crucial information that could affect their willingness to continue their participation.

Studies that recruit minors must anticipate their emancipation and make accommodations to ensure that the IC process facilitates independent/autonomous decision making.

The PI or his/her designee must obtain formal consent and authorization from these subjects to sustain participation in the study in one of the following ways:

- a) If the study has an adult consent form, the subject may sign the most recent adult consent form, subsequent to fulfillment of the informed consent process.
- b) If the study utilizes a consent form on which the minor subject signs his/her assent, the subject may sign the most recent version of the consent for him/herself on the participant line OR sign the most recent version

for him/herself on the parent line and note the relationship to the subject as self. The investigator(s) may also decide to create a separate adult consent form for participants 18 years of age or older.

- c) If the subject is no longer actively participating, but consent/authorization is needed for continued access to the individual's medical record for follow-up, verbal consent may be obtained. The consent script should be submitted to the IRB for approval and the verbal consent should be documented in the research record.

Additionally, the subject's birthday (or reason for emancipation) should be noted on the consent form and in the research record during the consent process to indicate that the individual is legally capable of providing consent.

### **Documentation Requirements**

FDA regulation 21 CFR 312.62(b) states "The case history of each individual shall document that informed consent was obtained prior to the participation in the study" for studies using either an experimental drug or device. The following must be documented in the research file by whomever conducted the IC process (the PI, his/her designee or other appropriate individual).

- Insert the newly executed informed consent document into the study file.
- Include a note in the study file (e.g. progress record) stating the inclusion/exclusion criteria for enrollment were met.
- Document that the purpose, procedures, risks, benefits and alternatives were discussed and accepted by the subject and that he or she had adequate time to ask questions and make an informed decision.
- Document that the subject received a copy of the newly executed informed consent document.

### **Research-Mandated Pregnancy Testing in Minors**

Study protocols that include drugs or treatments that have the potential to cause harm or death to a fetus should require pregnancy testing as part of the subject's participation. Pursuant to Illinois State Law, protocols that require pregnancy testing of minors must include a statement in the informed consent document indicating that

the test results cannot be reported to a parent or legal guardian without the minor's agreement.

### **IRB Review Requirements**

Federal regulations require the IRB to classify research involving children into one of the above four categories and to document their discussions of the risks and benefits of the research study in the IRB minutes.

Reference

45 CFR 46, Subpart D, 21 CFR 50, Subpart D,  
RUMC Policy #OP-0029, Illinois State Law 410 ILCS 210/1

**Last Reviewed: 5/13/2014**