Federal regulations ([45 CFR 46 Subpart D](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6) and [21 CFR 50 Subpart D](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.4)) require that additional protections be put into place if children are to be recruited and enrolled as subjects in research. Other federal regulations, state law, and organizational requirements (for example, requirements of the Chicago Public Schools Research Review Board) may also apply.

**I. Research Title:**

**II. Children Subject Population**

**A. Age Range (check all that apply):**

[ ]  Newborn to 2 years of age [ ]  13-15 Years

[ ]  3-6 Years [ ]  16-17 Years

[ ]  7-12 Years

**B. Please identify which federally-defined category applies to this research.**

1. [ ]  [**45 CFR 46.404**](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1404)(FDA [21 CFR 50.51](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.51))

* Research involves no greater than minimal risk to children AND
* Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian

2. [ ]  [**45 CFR 46.405**](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1405)(FDA [21 CFR 50.52](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.52))

* Research involves greater than minimal risk to children BUT
* Presents the prospect of direct benefit to the individual child AND
* Anticipated benefit justifies the risk AND
* Anticipated benefit versus the risk is at least as favorable as that of alternative approaches AND
* Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian

3. [ ]  [**45 CFR 46.406**](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1406)(FDA [21 CFR 50.53](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.53))

* Research involves greater than minimal risk to children AND
* Presents no prospect of direct benefit to the individual child BUT
* The risk represents a minor increase over minimal risk AND
* Interventions or procedures present experiences that are reasonably commensurate with those inherent in the child’s actual or expected medical, dental, psychological, social, or educational situations AND
* Interventions or procedures are likely to yield generalizable knowledge about the child’s disorder or condition that is of vital importance for the understanding or amelioration of the child’s disorder or condition AND
* Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian**.**

4. [ ]  [**45 CFR 46.407**](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1407)(FDA [21 CFR 50.54](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.54))

* Research not otherwise approvable under one of the above categories BUT
* Presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children AND
* Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian

a. Explain why the proposed research presents an opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:

|  |
| --- |
| Research in category 45 CFR 46.407 / 21 CFR 50.54 must be sent to a federal panel (or to a UIC-convened panel of experts if the research is not federally-funded or under the purview of the FDA) for determination before final IRB approval can be obtained, and the recruitment and enrollment of subjects can begin.  |

**C. Will research involving children be conducted outside the state of Illinois?**

[ ]  No

[ ]  Yes – For each state in which the research will be performed, provide the definition of “child” and “legally authorized representative” or “guardian” FOR RESEARCH PURPOSES:

**D. Children Who Are Wards** [**45 CFR 46.409(a)**](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1409) **(FDA** [**21 CFR 50.56(a)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.56)**)**

1. Does the research involve wards of the State or wards of any other organization?

[ ]  No – *Skip to Section III.*

[ ]  Yes – if research meets criteria B.1.([46.404](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1404)) or B.2.([46.405](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1405)), *skip to Section III*.

[ ]  Yes – if research meets criteria B.3.([46.406](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1406)) or B.4.([46.407](https://www.ecfr.gov/cgi-bin/text-idx?SID=03909697bcc8b696c58748b220bf9270&mc=true&node=sp45.1.46.d&rgn=div6#se45.1.46_1407)):

a. Is the research related to their status as wards?

[ ]  No – *Skip to Section III*.

[ ]  Yes – Explain why the proposed research presents an opportunity to further the understanding of issues related to the status of children as wards:

**Note:** For research that focuses on wards as a subject population, provide documentation verifying the appointment of an independent Ward Advocate for each ward. Pending documentation may be submitted under an Amendment upon availability; however, this is required before the ward may be enrolled in the research.

**Ward Advocates:**

* Have the background/experience to act in the best interests of the ward for the duration of the ward’s participation in the research
* Are NOT affiliated with the research, the research organization, or the ward’s guardian organization (for example, the State or DCFS)
* One individual may serve as Ward Advocate for more than one ward

**III. Procedures to Obtain Assent**

The assent of the child plus the permission of the parent(s)/guardian(s) must be obtained prior to a child’s recruitment or enrollment as a research subject. Given adequate justification, the IRB may waive child assent and/or parent/guardian permission **unless the research is FDA-regulated as parent/guardian permission is ALWAYS required for FDA-regulated research.**

Under Illinois law, some older children may have a qualified or limited capacity to consent to participation in certain types of research without the permission of their parent/guardian. *Please refer to UIC HSPP policy* [*Research involving Children (including Wards of the State)*](https://go.uic.edu/irb0910)*.*

**A. Assent**

Federal regulations require the IRB to determine that adequate provisions are made for soliciting the assent of children when, in the judgment of the IRB, the children are capable of providing assent.

1. Will assent be obtained from all children?

[ ]  Yes – *Skip to question 2.a.*

[ ]  No – Select all that apply:

a. [ ]  All children or [ ]  Some children will be unable to provide assent because of their age, maturity or psychological state, or because their capability is so limited that they cannot be reasonably consulted.

Explain:

b. [ ]  Assent from children will not be obtained because the research is minimal risk and meets the adult criteria for waiving consent (e.g., research is limited to a retrospective chart review or secondary analysis).

c. [ ]  The intervention(s) or procedure(s) involved in the research hold out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

Explain what assent processes or procedures will ensure that the child’s autonomy and right to justice are respected (Note that 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 the research, the IRB may determine that a child’s dissent, which should normally be respected, may be overruled by the child’s parents or legal guardian):

2. a. Provide a detailed explanation of the procedures to be used to solicit the assent or assess the dissent of children and how this will be documented (Note: If 1.b. is the ONLY option selected above, skip to section B.):

b. For children who cannot verbalize assent, describe behaviors that will be viewed as indicators that the child does not wish to participate in the research (e.g., crying, moving away from the investigator, being unwilling to complete tasks).

c. Detail the proposed additional safeguards that will be put into place to ensure that children understand and freely volunteer to participate in the research (for example, plans for on-going evaluation of the child’s assent, independent witness observation of the assent process, involvement of a subject advocate). **Special attention should be paid to avoiding coercion or undue influence of the potential child subjects.**

d. If enrolling children whose primary language is not English, explain how and who will be responsible for conducting/overseeing the assent process.

[ ]  N/A – Only children whose primary language is English will be enrolled.

**B. Parent/Guardian Permission**

1. Indicate the type(s) of Parental Permission you will obtain:

[ ]  Written

[ ]  Verbal/Waiver of Signed permission form

[ ]  Waiver of Parental Permission for a portion of the research - Explain:

[ ]  Waiver of Parental Permission for all of the research - Indicate the justification for not obtaining permission from parent(s)/guardian(s) by selecting a. or b. below, then skip to item C. (Note: A waiver of Parental Permission can NOT be granted if the research is FDA-regulated.)

a. [ ]  Parent/guardian permission will not be obtained because the research is minimal risk and meets the adult criteria for waiving consent (e.g., research is limited to a retrospective chart review or secondary analysis).

b. [ ]  Soliciting permission would not protect the child (for example: neglected or abused children) and alternative, appropriate safeguards for protecting the child will be put into place.

i. Explain why obtaining parent/guardian permission would not protect the child:

ii. Provide a detailed outline of the alternative, appropriate safeguards that will be put into place to protect the child:

2. a. Provide a detailed explanation of the procedures and/or documentation to be used to solicit the permission of parent(s)/guardian(s).

1. Explain how the authority of the parent(s)/guardian(s) to give permission for the child to be involved in research will be verified (for example, verifying the identity of the legal custodial parent or guardian where the parents are divorced). **The research purpose, research context, and/or subject population may warrant special attention to the verification of the authority of parent(s)/guardian(s)**:

c. Where the research purpose, research context, and/or subject population warrant the verification of the legal authority of the parent/guardian, will documentation of the parent’s/guardian’s authority be reviewed by the investigator and/or copies collected from each parent/guardian (including, but not limited to, court orders or guardianship documents)?

[ ]  N/A – Research purpose, research context, and/or subject population do NOT warrant the verification of the legal authority of the parent/guardian

[ ]  Yes

[ ]  No -Provide justification for NOT reviewing or collecting documentation of the legal authority of each parent/guardian:

d. Indicate where and when permission will be obtained from parents/guardians. The timeline for obtaining permission should take into consideration any events or stressors that may affect the parent’s/guardian’s ability to make an informed decision (e.g., does the research require that parent/guardian permission be obtained immediately after diagnosis of the child’s serious illness?).

e. Indicate whether permission will be obtained using procedures and documents in the primary language of the parent/guardian, particularly if parent’s/guardian’s primary language is NOT English:

[ ]  N/A – Only English-speaking parents/guardians will be solicited for permission

[ ]  Permission process will be conducted in the parent’s/guardian’s primary language(s) **AND the child subject will NOT be used as a translator**

Specify language(s):

[ ]  Permission documents will be translated into the parent’s/guardian’s primary languages(s)

Specify language(s):

Please note that a “short form” and translation process may be used when the enrollment of a limited number of non-English speaking parents/guardians **could not reasonably have been anticipated** and a fully translated consent document is not available. For information about the short form, please refer to the [OPRS website](http://research.uic.edu/human-subjects-irbs/) at: <https://research.uic.edu/human-subjects-irbs/getting-started-preparation-for-submission/forms/> (look under “Informed Consent Short Forms for persons who do not read English”).

**C. Re-Consent process for minors who become adults during the study**

Will any of the children originally enrolled by assent and/or permission from their parents or guardian reach the age of majority (18 years or old) while participating in this study?

[ ]  No

[ ]  Yes - Describe how legally effective consent will be solicited and obtained from the now-adult subjects.