I. Children are considered by the federal regulations as being vulnerable to coercion. To safeguard their interests and protect them from harm, additional regulatory protections exist for research involving children. The UIC IRBs approve research involving minors only if the research complies with the safeguards described in this policy and procedure.

II. In its FWA, UIC has elected to not extend OHRP’s authority to all human subjects research conducted at UIC; however, the general protections of the Belmont Report and the Common Rule [45 CFR 46] will be applied to all research reviewed and approved at UIC either in the same way or an a comparable variation. For both federally and non-federally funded research involving children as subjects, the IRB follows federal regulations at 45 CFR 46 Subpart D and 21 CFR 50 Subpart D, in addition to those imposed under UIC HSPP policies, ethical considerations and other applicable Federal, state and local laws for review and approval.

III. It should be noted that the Departments of Education and Defense have adopted Subpart D, but the National Science Foundation has not; however, UIC policy affords the same protections to children regardless of the funding source and parallels the additional protections afforded to children as codified in Subpart D to all research involving children.

IV. Definitions.

A. ASSENT: a child's affirmative agreement to participate in research. The child’s failure to object, absent affirmative agreement, should not be considered assent.

B. CHILD/CHILDREN/MINORS: The federal research regulations define children as individuals who have not attained the legal age for consent to treatments or procedures involved in the research, under the State or local law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)). In Illinois, a minor is defined as an individual under the age of 18 years (325 ILCS 45/2(c)) with the exceptions described below.

C. FOSTER CHILD: In Illinois, a foster child is a ward of the state since the Illinois Department of Children and Family Services, an Illinois state agency, holds guardianship of the person for foster children. (Juvenile Court Act of 1987, 705 ILCS 405; Children and Family Services Act, 20 ILCS 505).
D. GUARDIAN: DHHS and the FDA define a guardian as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In Illinois, the term Guardian “means a court appointed guardian of the person who serves as a representative of a minor or as a representative of a person under legal disability.” In Illinois, a variety of guardianship appointments exist and the investigator should take care to document that the guardian’s representation of the ward for the research is within the scope of their authority: limited guardianship, plenary guardianship, guardian of the person, guardian of the estate, and temporary guardianship. (Health Care Surrogate Act, 755 ILCS 40; Juvenile Court Act of 1987, 705 ILCS 405/1-2).

E. GUARDIANSHIP OF THE PERSON OF A MINOR: In Illinois, the duty and authority to act in the best interests of the minor, subject to residual parental rights and responsibilities, to make important decisions in matters having permanent effect on the life and development of the minor and to be concerned with his or her general welfare. It is includes but is not necessarily limited to . . . the authority to consent to major medical, psychiatric, and surgical treatment. (Juvenile Court Act of 1987, 705 ILCS 405/1-2). Please contact OPRS for guidance in temporary custody situations or for children who are placed by court under the guardianship of a probation officer, as these are complex situations that may require the advice of University Counsel.

F. WARD: A ward means any child who is placed in the legal custody of the state or other agency, institution, or entity, consistent with the applicable federal, state, and local laws and regulations. (21 CFR 50.3(g). In Illinois, a ward of the state includes but is not limited to a child placed by court under the guardianship of the Illinois Department of Children and Family Services. In Illinois, children placed in foster care are wards of the state. (Juvenile Court Act of 1987, 705 ILCS 405/ 2-7).

V. Circumstances When Minors Can Consent for Themselves.

A. Emancipated or Mature Minor. If a minor has been adjudicated as a “mature minor” or an “emancipated minor” by an Illinois court with jurisdiction over such minor, such minor would also be able to consent to medical treatment and research relating to such treatment under Illinois law. Note that if a minor has only been partially emancipated under the Emancipation of Minors Act, such minor will only have those rights and responsibilities as specified in the court order. When research involves subjects who claim that they are “emancipated” or “mature” minors, the investigator must review and document in the research record the court order that provides such designation before allowing such subject to consent as an adult for the research. An individual aged 17 who is enrolled in the military is also not considered a minor under some circumstances in Illinois.

B. Illinois law also grants minors the legal capacity to consent to medical treatment in certain situations. The Illinois Consent by Minors to Medical Procedures Act (410 ILCS 210/1) permits:
1. A married minor, a minor parent, or a pregnant minor to provide his or her own informed consent to the performance of a medical or surgical procedure performed by: (i) a physician licensed to practice medicine and surgery, (ii) an advanced practice nurse who has a written collaborative agreement with a collaborating physician that authorizes provision of services for minors, or (iii) a physician assistant who has been delegated authority to provide services for minors.

2. A minor parent to provide the informed consent for performance on his or her child of a medical or surgical procedure by a physician licensed to practice medicine and surgery, an advanced practice nurse who has a written collaborative agreement with a collaborating physician that authorizes provision of services for minors, or a physician assistant who has been delegated authority to provide services for minors, or a dental procedure by a licensed dentist.

3. Other instances where the Minors Medical Procedures Act deems a minor to have the same legal capacity to consent as an adult include:
   a. Emergency treatment or first aid or emergency dental treatment. (410 ILCS 210/3(a)).
   b. Medical care or counseling related to the diagnosis or treatment of any disease or injury arising from predatory criminal sexual assault of a child, aggravated criminal sexual assault, criminal sexual assault, aggravated criminal sexual abuse or criminal abuse of a child. (410 ILCS 210/3(b)).
   c. Medical care or counseling related to the diagnosis or treatment of a minor 12 years of age or older who may have come into contact with any sexually transmitted disease (STD), or may be determined to be an addict, an alcoholic or an intoxicated person, or who may have a family member who abuses drugs or alcohol. (410 ILCS 210/4).

4. The UIC IRB extends the provisions of the Minors Medical Treatment Act to research. Specifically, under the circumstances or for the conditions stipulated in the Act, the UIC IRB views the minor to have the same legal capacity to act and has the same powers and obligations as has a person of legal age to consent for research involving such medical or surgical procedures. The minor is not deemed to be able to provide consent for research involving conditions not stipulated by the Act or involving medical or surgical procedures not covered by the Act. Thus, a 13 year old male seeking medical treatment for alcohol addiction can consent to participate in research involving addiction treatment. The research may not however involve additional activities unrelated to clinical management of the addiction, such as genetic research.

5. A minor who is able to give consent (as described in IV A.-B. above) under Illinois State Law is not considered a child under federal regulations.
VI. When assent is required by the IRB, the decision of the child assenting is binding, provided parental or guardian permission, when necessary, has been obtained.

VII. When the duration of the children’s participation in a research project may continue beyond the age of majority, the investigator must include provisions for obtaining the legally effective consent from the now-adult participants for proceeding with their research participation.

VIII. A UIC investigator applying to conduct a research activity involving children in another jurisdiction (i.e., state) must become familiar and provide evidence of compliance to the IRB with all applicable legal, professional, and ethical requirements for the conduct of research involving children for each jurisdiction where the research will be conducted.

IX. Studies that involve children or other vulnerable populations, are greater than minimal risk and are not conducted in Illinois must be reviewed and approved by an IRB in the appropriate jurisdiction (i.e., state) as well as the UIC IRB.

X. VA Research reviewed by CHAIRb: Research involving children cannot be conducted by VA investigators while on official VA duty, using VA resources, completely or partially in a VA facility or at a VA-approved off-site facility unless a waiver has been granted by the CRADO and research is not greater than minimal risk. Research involving biological specimens or data obtained from children is considered by the VA to be research involving children.

A. IRB approval obtained in accordance with 45 CFR 46, Subpart D and 21 CFR 50; and

B. VA R&D approval obtained; and

C. Waiver from VA Chief Research & Development Officer (CRADO).

PROCEDURES:

I. IRB Responsibilities.

A. As part of their determination, based upon risk and benefit, the IRB must consider additional safeguards that are appropriate to the subject population, classify research involving children into one of four categories, document its discussions of the risks and benefits of the research study, and make appropriate determinations as to permission from the parent or guardian and assent from the child.

B. When reviewing research involving children, the IRB chair will ensure that at least one member with experience in research involving children is present at the meeting. If necessary expertise is not available among the members, the services of an ad hoc consultant with appropriate experience will be sought.

C. For FDA-regulated research, the UIC IRB reviews the proposed research in accordance with 21 CFR 50 Subpart D.

II. Categories of Research Involving Children. For these categories, 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. (45 CFR 46.102). Please review Table I below for detailed information as to approval criteria by category. The second column details what the IRB must find and document protocol specific information in review guides for expedited review or meeting minutes for convened review.

Table I: Approval Criteria for Categories of Research Involving Children.

<table>
<thead>
<tr>
<th>Category 1: Research Not Involving Greater than Minimal Risk (45 CFR 46.404; 21 CFR 50.51)</th>
<th>Permission of one parent is permitted if approved by the IRB. Or IRB may require permission of both parents unless: 1. One parent is deceased, unknown, incompetent, not reasonably available, or 2. Only one parent has legal responsibility for care and custody of child.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The research presents no more than minimal risk to the children; and 2. Adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians as set forth at 46.408 (see Section III).</td>
<td></td>
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<table>
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<tr>
<th>Category 2: Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Child (45 CFR 46.405; 21 CFR 50.52)</th>
<th>Permission of one parent is permitted if approved by the IRB. Or IRB may require permission of both parents unless: 1. One parent is deceased, unknown, incompetent, not reasonably available, or 2. Only one parent has legal responsibility for care and custody of child.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The research presents more than minimal risk to the children by an intervention or procedure that holds out the prospect of direct benefit for the individual child, or by a monitoring procedure that is likely to contribute to the child’s well-being; 2. The risk is justified by the anticipated benefit to the child; 3. The relation of the anticipated benefit to the risk is at least as favorable to the children as that presented by available alternative approaches; and 4. Adequate provisions are made for obtaining the assent of the child and permission of their parents or legal guardians as set forth at 46.408 (see Section III).</td>
<td></td>
</tr>
</tbody>
</table>
**Category 3: Research Involving Greater than Minimal Risk and No Prospect of Direct Benefit to the Individual Child, but Likely to Yield Generalizable Knowledge about the Child’s Disorder or Condition.** (45 CFR 46.406; 21 CFR 50.53).

1. Greater than minimal risk is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual child, or by a monitoring procedure which is not likely to contribute to the well-being of the child;  
2. Risk represents a minor increase over minimal risk;  
3. 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;  
4. 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  
5. Adequate provisions are made for soliciting assent of the children and permission of their parents or legal guardians.

Permission of both parents is required unless:  
1. One parent is deceased, unknown, incompetent, not reasonably available, or  
2. Only one parent has legal responsibility for care and custody of child.

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**Category 4: Research Not Otherwise Approvable, which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children** (45 CFR 46.407 and 21 CFR 50.54).

For research where the IRB finds the research does not meet the requirements set forth in categories 46.404, 46.405 or 46.406 as described above in this table, the IRB may approve the research only if:  
1. The 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  
2. If Federally funded or under the purview of the FDA, the Secretary of DHHS or, if applicable, FDA Commissioner, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either:  
   A. That the research in fact satisfies the conditions of categories 46.404, 46.405, or 46.406; or

Permission of both parents is required unless:  
1. One parent is deceased, unknown, incompetent, not reasonably available, or  
2. Only one parent has legal responsibility for care and custody of the child.

For research that is not federally funded or under the purview of the FDA, and the IRB determines such research falls within category 46.407, the UIC IRB will provide copies of the protocol and the IRB
B. The following:

1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
2. The research will be conducted in accordance with sound ethical principles; and
3. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

minutes to the HPA for a determination regarding whether an ad hoc panel of experts should be convened to review the research in a process parallel to that of OHRP expert panel review. In this case, UIC IRB approval will not be released until either the HPA determines an ad hoc panel is not necessary or the ad hoc panel issues a recommendation that the research is acceptable.

B. The following:

1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
2. The research will be conducted in accordance with sound ethical principles; and
3. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

III. VA Research reviewed by CHAIRb and Involve Children.

A. A waiver from the CRADO is required before research involving children and reviewed by CHAIRb may be performed at JBVAMC and/or Hines VA. The following criteria must be met before requesting the waiver:

1. IRB determines the study represents no greater than minimal risk;
2. study meets all requirements in 45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research, Sections 46.401 through 46.404, and 46.408;
3. IRB reviewing the study has appropriate membership to represent children's interests and pediatric expertise;
4. IRB reviewing study has SOPs regarding children in research;
5. VA Facility Director certifies that facility is able to respond to pediatric emergencies if the study includes interactions with children at the VA facility; and
6. If the VA is not the sponsor, Facility Director makes certain that the sponsor of the research has procured appropriate liability insurance.

B. To request a waiver, the following information must be submitted to ORD:

1. Cover letter signed by the Facility Director containing the following:
   a. certification by the Facility Director that the facility is able to respond to pediatric emergencies if the study includes an interaction with children at the VA facility;
   b. any additional safeguards that have been incorporated into the clinical site where children will be studied;
   c. information on the study’s funding source and on liability coverage if the sponsor is not VA;
   d. certification that the IRB has determined the study to be of no greater than minimal risk and has approved the study;
   e. statement that the required elements of 45 CFR 46 Subpart D have been met; and
   f. description of the relevance to Veterans' health of both the study and inclusion of children in study.
2. Copy of study protocol, informed consent form (i.e., parent or guardian permission), assent document, and HIPAA authorization. Provisions for permission by parents or guardians must be documented in accordance with and to the extent required by 38 CFR 16.117 (see VI. below).

3. Minutes of the IRB meeting approving the study. IRB minutes need to reflect discussion regarding risk level, informed consent (parental permission) and assent forms, investigators’ qualifications to conduct research involving children, and any additional safeguards incorporated into the protocol.

4. If the study involves biological specimens or data collected from children, in addition to the preceding requirements, the following must be submitted:
   a. discussion of how biological specimens or data were, or will be, obtained and under what consents or authorization;
   b. if the biological specimens or data were, or will be, collected for research purposes, IRB approval, informed consent (parental permission) form, and the HIPAA authorization for the research;
   c. if biological specimens or data were, or will be, collected from an international site, waiver from the CRADO for international research; and
   d. plans for future use of biological specimens or data.

IV. Requirements for Obtaining Assent from Children.
   A. The IRB must find 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.
   B. The IRB in judging whether children are capable of assenting must take into account the ages, maturity, and psychological state of the children involved.
   C. When the IRB determines that assent of a child is required, it shall also determine whether and how assent must be documented.
   D. The IRB may make the judgment concerning capability to assent either for all children, just some, or none of the children to be involved in the research. When assent is not required for some children, the IRB documents which children are not required to assent.
   E. The UIC IRB generally requires assent from children ages seven years and older, unless the IRB finds their capability to provide assent is compromised. However, the IRB may at their discretion extend this requirement to children younger than 7 years for certain types of research.
   F. The assent should provide the child with an explanation of the proposed research procedures and an understanding of what is being requested of them in a format (i.e., oral and/or written) and language that is appropriate to the child’s age, experience, maturity, and condition.
   G. For children between 7 to 12 years of age, the assent should be limited to 1 page and focus on describing what participation in the research will entail, such as what activities will occur, how long it will take, and whether it may involve any pain or discomfort. The use of illustrations or diagrams is
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encouraged with this age group. The assent is generally presented orally to
the child with a written document (i.e., script of presentation) available for the
child to document their assent.

H. For children older than 12 years of age, an assent written in age-appropriate
language and containing the same elements as in an adult consent form
should be provided. In fact, older children, e.g., 16 or 17 years of age, due to
their higher maturity and cognitive ability may be able to read, understand,
and subsequently sign the adult consent document.

I. The investigator must describe the procedures to be used for soliciting assent
in UIC OPRS form Appendix B.

V. Waiver of Assent.

A. The assent of a child is not a necessary condition for proceeding with the
research (i.e., it may be waived) if the IRB determines and provides protocol
specific information documenting that:

1. Children are not capable of providing assent based on their age, maturity
or psychological state;

2. The capability of some or all of the children is so limited that they
cannot reasonably be consulted; or

3. 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.

B. Even where the IRB approves a waiver of assent, it is generally desirable to
still provide the child with an understanding of the research. The IRB may
require the investigator to prepare an “information sheet” that provides the
child with an explanation of the study in a format (oral and/or written) and
language appropriate for the child’s age, experience, maturity and condition.

1. A decision by the IRB that the children are capable of assenting does
not prevent the IRB from waiving assent under the conditions for which
consent may be waived at 45 CFR 46.116(d)(1-4):

   a. the research involves no more than minimal risk to the subject;

   b. the waiver or alteration will not adversely affect the rights and
      welfare of the subjects;

   c. the research could not practicably be carried out without the
      waiver or alteration; and

   d. whenever appropriate, subjects will be provided with additional
      pertinent information after participation.

VI. Provisions for Obtaining Permission from Parents or Legal Guardians.

A. The IRB must find that adequate provisions are made for soliciting the
permission of each child's parents (or guardians).

B. The permission form provided parents or guardians must contain the basic
elements of consent as stated in 45 CFR 46.116(a) (1-8) and 21 CFR
50.25(a)(1-8) and any additional elements the IRB deems necessary.

C. Permission by parents or guardians must be documented in the same manner
as required for informed consent of subjects.

D. The investigator must describe the procedures to be used for obtaining
VII. Waiver of Parent or Guardian Permission. The IRB may waive the requirement for obtaining permission from parents or guardians when:
   A. the research does not fall under FDA regulations, and
   B. the research either:
      1. meets the provisions for waiver in 45 CFR 46.116(d)(1-4), see above, or
      2. the IRB determines that the research is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).
   3. When the requirement for parental or guardian permission is waived according to above, an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. Also, the waiver must not be inconsistent with federal, state or local law. Selection of an appropriate mechanism is guided by the nature and purpose of the research activities, the risk and anticipated benefit to the subjects, and their age, maturity, status, and condition.

VIII. Investigator Responsibilities.
   A. Investigators are responsible for determining any changes in the legally authorized representative status for children participating in research for all cases with vulnerable populations.
   B. The investigator must be particularly attentive with wards, since the legally authorized representative may change if the ward is adopted or if the parents regain guardianship.
   C. The investigator must perform one of the following at minimum:
      1. Periodically assess with an adult accompanying the child if there has been a change in guardianship;
      2. Including a statement in the informed consent form that the guardian should inform the investigator when there is a change in the guardian status; and
      3. Any other methods to ensure prompt notification of a change in guardianship status.

IX. Wards.
   A. For research conducted with wards in Illinois, the UIC IRB must receive documentation of Illinois Department of Children and Family Services (DCFS) approval for wards of this department prior to approving any research involving DCFS wards.
   B. For foster children, the UIC IRB must also follow the specific foster agency requirements concerning the appointment of an advocate as provided by the investigator.
   C. Children who are wards of the State or any other agency, institution, or entity can be included in research approved under 45 CFR §46.406 or §46.407 only if such research is:
1. Related to their status as wards; or
2. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

D. If the research is approved under 45 CFR §46.406 or §46.407, the IRB must 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 must 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.

E. Illinois DCFS Criteria for Approval of Research Involving Children.

1. Investigators contemplating a request that the UIC IRB review whether wards may be included to the population cohort of a research protocol should note that DCFS has different definitions for terms used in the Common Rule [45 CFR 46] to afford greater protections to wards. For example: The DCFS definition of “Maximum Allowable Risk” means “the greatest possible risk [DCFS] will permit to the children and families it serves. This risk must not be greater overall than would normally encountered in the daily lives or in the routine medical or psychological care or examination of a comparable group of Illinois children for whom [DCFS] is not legally responsible. Since abused, neglected, dependent and other children for whom [DCFS] is legally responsible and their families may already be psychologically or physically disadvantaged compared to the general population of children or families, minimal risk requirements for these children and families will be more stringent than for the general population.” (89 ILADC 432)

2. The DCFS “Research Review Board” must first approve the research before the UIC IRB can review the research. Investigators should note that documentation of approval from DCFS is required prior to submission to the UIC IRB. Please allow sufficient time for DCFS to process this submission.

3. The DCFS “Research Review Board” “will receive, review and analyze all proposed research which would involve children and families served by [DCFS], or records of such children and families, and research proposed by [DCFS] providers.” (89 ILADC 432).

4. The criteria by which proposed research will be evaluated by DCFS:
   a. Offers minimal risk to children and families served by [DCFS];
   b. Assures that the safest procedures are used consistent with sound research design and methodology;
   c. Makes adequate provision to protect the privacy rights of children and families and to maintain confidentiality of records;
   d. Maintains human dignity;
   e. Shows promise of producing, confirming or otherwise advancing knowledge of child or family emotional or physical conditions;
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f. Assures that subjects will be selected in an equitable manner consistent with the goals of the research whenever appropriate;

g. Assures that adults, older children and infants have been considered in that order for participation in the proposed research whenever appropriate; AND

h. Assures that, when feasible, the research will be used for diagnostic and treatment purposes to directly benefit participating subjects. (89 ILADC 432).

i. In addition, the following two criteria will also be used in the evaluation:

(1) The time and inconvenience requested of children and families participating in research and the extra workload that may be borne by [DCFS] staff must be justified by the expected benefits derived from the research, and the soundness of the research design.

(2) Selection of children and families who may participate in research will not be based solely on administrative convenience, availability of a populations living in conditions of social or economic deprivation, or convenient access to the population. (89 ILADC 432)

5. The Illinois Administrative Code provides “no experimental use of a drug may be made, and no drug of an experimental nature may be given or administered in any form or manner to any minor under the care of the [DCFS], except when this department has the power to consent to major medical treatment and procedures and when, in the opinion of the treating physician and of at least two medical experts not professional associated with the recommending physician, the administration of an experimental drug would represent the best possible change of saving the minor’s life or achieving the remission of a progressive, crippling, disfiguring, or potentially fatal disease. This provision is at all times subject to court review.” (89 ILADC 432)

F. Investigator Responsibilities.

1. Investigators should note, however, the restrictions and additional protections required for subjects who are wards when considering the initial research design. UIC OPRS recommends that individuals who would like to enroll wards contact UIC OPRS staff for guidance. UIC OPRS also recommends that investigators who are not anticipating a large cohort of the study population to be wards to first submit the protocol for approval without including the ward population. Once the underlying research is approved by the IRB, then the investigator should submit an amendment to add the ward population.

2. The investigator has a responsibility to disclose whether he or she believes that wards of the state could be recruited after approval is granted as part of the application process.

3. Investigators have an ongoing responsibility to immediately notify the IRB and OPRS and submit an amendment when an enrolled subject becomes a ward of the state while the research is active.
4. Investigators have a responsibility to be familiar with the specific requirements of foster agencies as to research with DCFS wards.

G. IRB Responsibilities.
   1. The IRB needs to follow the recommendations of the foster agency as to the appointment of an advocate if the foster agency requires the appointment of an advocate regardless of risk.
   2. The IRB has the responsibility to make protocol-specific findings as to the ward of the state regulatory criteria, which UIC OPRS staff has a responsibility to document in the meeting minutes.

REFERENCES:

Children
45 CFR 46 Subpart D; 21 CFR 50 Subpart D
VHA Handbook 1200.05
325 ILCS 45/2(c),

Wards
Permanency Advocacy Services, 89 ILADC 327.5
Research Involving Children and Families, 89 ILADC 432
Juvenile Court Act of 1987, 705 ILCS 405/1-2

REVISION LOG:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
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<tr>
<td>1.1, 3/13/09</td>
<td>1.0, 2/13/09</td>
<td>Changed the title from “Research Involving Children” to “Research Involving Children (Including Wards of the State).”</td>
</tr>
<tr>
<td>1.2, 6/18/09</td>
<td>1.1, 3/13/09</td>
<td>Removed citation to ILCS from definition of child.</td>
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<tr>
<td>1.3, 3/10/12</td>
<td>1.2, 6/18/09</td>
<td>Updated VA requirements due to 2010 revision of VHA Handbook 1200.05; Added reference to Department of Defense regulations</td>
</tr>
<tr>
<td>1.4, 9/27/16</td>
<td>1.3, 3/10/12</td>
<td>Formatting; Specify that VA research is limited to research reviewed by CHAIRb.</td>
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