ILLINOIS
Office for the Protection of Research Subjects

Research Guidance Document

RESEARCH INVOLVING WARDS OF STATE

Definitions

Ward: A *ward* is a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law. The term "ward of State" may be used interchangeably with "ward" in this document. A court may take responsibility for the legal protection of the individual, and will generally stand *in loco parentis* to the child. Generally, this entails assuming all lawful authority to make medical and legal decisions on the individual's behalf. In Illinois wards are called "Youth in Care".

Federal Research Regulations

Federal regulations may require additional safeguards for research involving wards of the state. These special protections are found in Subpart D (Additional Safeguards for Children Involved in Research). In order for the IRB to determine whether additional safeguards will be required for wards of the state, the IRB must first determine which approvable category the children's research falls under. The categories are as follows:

(1) Research involving no greater than minimal risk. [45 CFR 46.404; 21 CFR 50.51]

(2) Research involving interventions or procedures that present greater than minimal risk but offers the prospect of direct benefit or may contribute to the well-being of the individual child. [45 CFR 46.405; 21 CFR 50.52]

(3) Research involving interventions or procedures that present a minor increase over minimal risk and no prospect of direct benefit to individual children, but likely to yield generalizable knowledge about the child's disorder or condition. [45 CFR 46.406; 21 CFR 50.53]

(4) Research not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research in this category must be reviewed and approved by the Secretary of DHHS or the Commissioner of the FDA. [45 CFR 46.407; 21 CFR 50.54]

For more information, please refer to **Research Guidance Document: Research Involving Children** and **Research Involving Individuals with Decisional Impairment**.

Description

Children who are wards of the state may be included in research. No additional regulatory protections apply if the research was approved under categories (1) and (2) above. However, because the state will likely stand *in loco parentis* for the child, obtaining and properly documenting parental permission and assent to include the child in the study may present unusual challenges for the investigator.

Obtaining and Documenting Valid Parental Permission and Assent

All investigators conducting studies involving wards of the state should address the following issues related to the consent process and documenting parental permission and assent:

1. Documentation should be obtained from all persons who provide "parental permission" for the ward. This means the guardian is required to provide a signature on the parental permission document. A Waiver of Documentation is not appropriate for the guardian, but may be utilized for the ward on a case-by-case basis.
2. The investigator should maintain documentation in their research files of guardian's official designation by the state as the person who may make medical and legal decisions for the ward.
3. The investigator must provide the IRB with a specific description of how the consent process will be handled for wards of the state. The description should include a contingency for re-consenting participants/their parents in cases where guardianship is returned to the former ward's biological parent(s) while they are participating in the study, as applicable.

Additional Protections for Studies that are Greater than Minimal Risk and Offer No Prospect of Direct Benefit to the Participant

The IRB may approve research involving wards approved under category (3) and (4) above only if such research is either:

a. Related to their status as wards; or

b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as children are not wards.

Additionally, the IRB must require appointment of an advocate for each child who is a ward. The advocate will serve in addition to any other individual acting on behalf of the child as guardian. 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 interest of the child for the duration of the child's participation in the research. The advocate must not be 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.

DCFS Approval Required

In addition, all research that includes Illinois wards (Youth in Care) and their families require approval by the Illinois Department of Children and Family Services (DCFS) IRB prior to the initiation of the research. Research involving staff, foster parents, grantees and contractors of DCFS may also require this DCFS IRB review. https://dcfs.illinois.gov/get-involved/impact-public-policy/irb.html

Points to Address

New Study Application:	1. **Participants Page #3**: Select "Wards of State". 2. **Consent Process Form**: Describe how the consent process will be handled for wards of the state. How will the investigator ensure the guardian who signs the parental permission document is legally appointed to make decisions for the ward? The investigator should indicate their agreement to maintain documentation in their research files of guardian's official designation by the state as the person who may make medical and legal decisions for the ward. 3. In question **11.3** indicate the status of the DCFS IRB application.

References & Links

Investigator Guidance Series: Research Involving Children	*To be updated*
Additional Protections for the Inclusion of Children in Research (OHRP): 45 CFR 46, Subpart D	*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd*
Additional Protections for the Inclusion of Children in Research (FDA): 21 CFR 50	*http://www.ecfr.gov/cgi-bin/text-idx?SID=3ec863fa084f2ce8d216709eb3e5505a&mc=true&node=pt21.1.50&rgn=div5*