

# Investigator Guidance Series

University of Utah Institutional Review Board

## RESEARCH INVOLVING WARDS OF STATE

### Definitions

**Ward:** A ward means 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.

### Federal Research Regulations

Federal regulations may require additional safeguards for research involving wards of 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 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 **Investigator Guidance Series: Research Involving Children**.

### Description

Children who are wards of State may be included in research. No additional regulatory protections apply if the research was approved under categories (1) and (2) above.

### Additional Protections for Wards of State

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.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.

# Investigator Guidance Series

University of Utah Institutional Review Board

## Points to Address

### New Study Application:

1. **Section 3.3, Vulnerable Population Groups:** Select "Wards of State".

## References & Links

*Investigator Guidance Series: Research Involving Children Additional Protections for the Inclusion of Children in Research (OHRP): 45 CFR 46, Subpart D Additional Protections for the Inclusion of Children in Research (FDA): 21 CFR 50*

[http://www.research.utah.edu/irb/guidelines/investigator\\_guidance.html](http://www.research.utah.edu/irb/guidelines/investigator_guidance.html)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.19.4>

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.