



Wards of the State

Policy

- Children who are Wards of the state may be included in research that presents minimal risk 46.404 (50.51) or greater than minimal risk with a prospect of direct benefit 46.405 (50.52) of subpart D
- Children who are Wards of the state may be included in research that presents greater than minimal risk with no prospect of direct benefit (46.406 (50.53) or 46.407 (50.54) only if the IRB determines and documents that such research is

Related to their status as wards; or

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

If wards are to be included in research with no prospect of direct benefit, the IRB shall appoint 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 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 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

If children who are Wards are to be included in any research study, the investigator must provide the IRB with detailed information about the proposed permission/assent process, as well as the identity and authority of the individuals who will provide permission for the Ward subjects

The Commonwealth of Massachusetts requires that they review and approve all requests for individual Department of Children and Families clients to participate in research. This includes children who are in DSS care or custody. This review is conducted by the Department of Children and Families Research Proposal Review Committee. Investigators are required to complete and submit the appropriate forms in order for this review to occur. No research may begin with a particular ward until approval is obtained.

Definitions

Ward A ward means any child who has been adjudged dependent by a court and who is under the care or custody of a public official or agency, including foster children, or any child under the control of DSS in the state of Massachusetts. This also applies to children in penal custody or otherwise detained within the criminal justice system.

Procedures

1. As part of the Children's Hospital protocol application process, investigators will be asked if at the time of application there a likely possibility that a protocol could involve children who are wards of the State as potential subjects, and if so does the investigator plan to offer the study to these wards.
2. If the investigator indicates that at the time of protocol application there is a likely possibility that a protocol could involve wards and the investigator wishes to offer the protocol to wards the IRB will make the required regulatory findings.
3. If there is a likely possibility that wards may be included in the research and the risk/benefit classification is greater than minimal risk with no prospect of direct benefit 46.406 (50.53 or 46.407 (50.54) of subpart D, the special regulatory provisions for wards will be followed. This includes documenting the required findings and the appointment of an advocate as necessary.
4. If the investigator does not initially anticipate the inclusion of wards in the protocol, but the circumstances change or a situation arises where the investigators wishes to include a ward, a protocol amendment must be submitted so that any required regulatory requirements may be fulfilled
5. The State of Massachusetts requires advance review and approval by Department of Children and Families *(DCF) , and in some cases a court, of all requests of children who are in DCF care or custody to participate in research. Requests must be directed to the DCF research proposal review committee. [Assistant Commissioner for Quality Improvement, Massachusetts Department of children and Families 24 Farnsworth Street, Boston, MA] The CCI staff, the Office of General Counsel, and the DCF liaison on the Child Protective Team must be made aware of such requests, since they may be contacted directly by DCF. In addition, they may be aware of factors unknown to the investigator that make such involvement inadvisable.
6. Investigators are responsible for determining any changes in a legally authorized representative (LAR) for children participating in research. The investigator will inform the CCI which method s/he will use for determining a change in the LAR, including: 1) periodically asking the accompanying adult if there has been a change in guardianship 2) including within the informed consent that the guardian should inform the investigator if there has been a change in status 3) other method that will be reasonably designed to ensure prompt notice of such changes, sufficient to protect the rights of children as human subjects under the circumstances presented in the study. Changes in LAR status may require obtaining permission for a newly appointed LAR in

order for the child to continue to participating in the research. The CCI or General Counsel should be contacted if this situation occurs for further guidance. They will work promptly with you to determine what is required.

7. It should be noted that parents of children in DCF care or custody may, and most often do, retain the right to consent to participation by their child in any medical or psychological research. However depending on the circumstances, DCF and even court consent may also be required. If the parent(s) has sole legal custody, only parental consent is necessary for the child to participate in a research study. If DCF has sole or joint legal custody and the parent(s) consent, then DCF is likely to consent absent special circumstances. DCF may withhold consent in situations in which parents cannot be located, a petition to terminate parental rights has been granted, a child has been surrendered for adoption, or reasons specific to a family's or child's circumstances and needs. If DCF withholds consent based solely on the absence of the family, it may seek judicial approval for the child's participation; it is unlikely that DCF will permit participation based solely on its administrative consent where a parent who has the right to consent cannot be located.
8. For situations when children begin a study and then are placed in DCF care, the investigator is required to let DSS know so they are aware of the participation and any questions can be addressed. Although an unlikely scenario If a child begins a study under DCF custody without any permission from the parent and the child is later reunited with the parent, parental permission must be obtained form the parent in order for the child to continue participation in the research
9. Since these situations are complex, investigators who wish to enroll wards should contact the CCI and Office of General Counsel for guidance in complying with all federal and state regulations pertaining to the inclusion of wards in research.
10. The meeting minutes and investigator approval letters will document the CCI protocol specific findings related to research involving wards of the state

Document Attributes

Title	Special Procedures for Wards of the State		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05, 06/20/05, 9/15/06 10/16/06
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