Wards of the State

Purpose

This policy describes the standards for the participation of wards of the state in research studies conducted at Boston Children's Hospital.

Policy

Special considerations must be made for research involving Wards of the State. There are both state and federal laws that regulate what is allowed and what must be done when a ward participates in a research study.

Ward or Ward of the State: 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 the Department of Children and Families (DCF) or the Department of Youth Services in the state of Massachusetts. This also applies to children in penal custody or otherwise detained within the criminal justice system.

Determination of Risk Level

The IRB will be guided in its review of research involving Wards of the State by the requirements of 45 CFR 46 Subpart D and 21 CFR 50 Subpart D. In the course of review, the IRB will make an independent determination of the risk level of such research as defined in 45 CFR 46.404-407 or 21 CFR 50.51-54

I. Research not involving greater than minimal risk

Wards may be included if the research meets the requirements of 45 CFR 46.404 or 21 CFR 50.51.

II. Researcher involving greater than minimal risk with a prospect of direct benefit

Wards may be included in research that meets the requirements of 45 45 CFR 46.405 or 21 CFR 50.52.

III. Research involving greater than minimal risk and no prospect of direct benefit to individual subject

Wards 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:

1. Related to their status as wards; **OR**
2. Conducted in schools, camps, hospital, institutions, or similar settings in which the majority of children involved as participants are not wards

Advocates

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*;

1. One individual may serve as advocate for more than one child;
2. 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;
3. 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.

Parent Permission and Child Assent as Required by HHS and FDA Regulations

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.

Massachusetts Requirements

Review by the State

Please note that in Massachusetts, the Department of Children and Families requires that any research study that will involve a child within the care or custody of the state to be submitted to the Department Research Proposal Review Committee for review and approval prior to obtaining consent from the parents or the state.

For more information on the process for submitting information to the state and seeking approvals for participation in research, please see the Massachusetts Department of Children and Families policy: ***https://www.mass.gov/doc/research-and-survey-approvals-policy/download***

Consent Requirements

Parents of children who are in the care or legal custody of a state agency retain the right to consent to participation by their child in any medical or psychological research.

- If the parent(s) has sole legal custody, parental consent is necessary for the child to participate in a research study, but the state is also required to approve of the child being enrolled as the child is in their physical custody.
- If a state agency has legal custody and the parent(s) approves, then the state agency will follow the parents wished and will also consent to the research provided that there are no casework reasons for denying consent (please note that if the parents do not consent or are not available to consent, then the state agency will seek judicial approval for the research
- Please note that regardless of who has custody, if the IRB determines in accordance with federal regulations pertaining to human subject protection that the permission of both parents is required, if reasonable available, this requirement will be applied.

Procedures

1. As part of the Boston Children's Hospital protocol application process, investigators will be asked at the time of application whether there is a likely possibility that a protocol could involve children who are wards of the state as potential subjects, and if so whether the investigator plans 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, pursuant to 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 parental consent and also a review by the Department of Children and Families *Department Research Proposal Review Committee* prior to a child's participating in research.

    a. 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 02210

    b. The IRB staff, the Office of General Counsel, and potentially the BCH Child Protective Program 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 IRB which method they will use for determining a change in the LAR, including:
    a. Periodically asking the accompanying adult if there has been a change in guardianship;
    b. Including within the informed consent that the guardian should inform the investigator if there has been a change in status;
    c. 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 participating in the research. The IRB 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 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.
    a. If the parent(s) has sole legal custody, parental consent is necessary for the child to participate in a research study, but the state is also required to approve of the child being enrolled as the child is in their physical custody
    b. If DCF has sole or joint legal custody and the parent(s) approve, then DCF will consent and follow the parent(s) wishes absent special circumstances.
    c. DCF will seek judicial approval for 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.
8. For situations in which children begin a study and then are placed in DCF care, the investigator should follow the process above for obtaining consent. 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 from the parent in order for the child to continue participation in the research.

Because these situations are complex, investigators who wish to enroll wards should contact the IRB and Office of General Counsel for guidance in complying with all federal and state regulations pertaining to the inclusion of wards in research.

The meeting minutes and investigator approval letters will document the IRB protocol specific findings related to research involving wards of the state.

Related Content

Massachusetts Policy

Massachusetts Department of Children and Families:
https://www.mass.gov/doc/research-and-survey-approvals-policy/download

Document Attributes

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