Children in State Custody

Purpose

This policy describes the standards for obtaining consent for children who are in the legal custody of a state agency to participate in a research study.

Definitions

Children in State Custody: Any child for whom a state agency (in Massachusetts this is the Department of Children and Family (DCF)) has obtained temporary or permanent legal custody of a child.

Please note that this definition and policy does not apply to children who are in the physical custody of the Massachusetts Department of Youth Services (DYS). Parents retain legal custody of children in DYS custody. However, please note that the DYS regulations also legally allow for a parent to delegate authority for medical decision making to the clinical staff at the DYS facility. Under BCH policies for delegated authority for consent, if the parents have signed this authorization, then the DYS facility's clinical staff are considered the legally authorized representative for providing consent for treatment as well as enrollment in a clinical research trial.

Policy

Special considerations must be made for research involving children where the state has assumed legal custody. While federal regulations outline the general requirements for children in state custody to participate in a research study, state policies provide specific guidance on who may consent for enrolling children in state custody in a research study.

State Criteria for Obtaining Consent to Enroll in a Research Study

For children residing in Massachusetts, there are two methods by which the Department of Children and Families (DCF) may be involved with a family. Only the first method (outlined below) will impact the process for obtaining consent to enroll into a research study (as documented in state regulations 110 CMR 11.23, and state policy (DCF Policy #91-005, revised 07/08/2008):

a) The first method is a Care and Protection (C&P), where DCF has obtained legal

custody through a permanent or temporary order and must provide the consent for enrollment in a research study. This includes the following considerations:

i. If the child is still residing with the parents or with family members, the study must obtain consent from the DCF social worker managing the case. The DCF social worker has authority through state regulations as the legally authorized representative of DCF to consent for care and treatment as well as enroll in a research study.

ii. If the child is in foster care, the study must also obtain consent from the DCF social worker managing the case, who is the legally authorized representative on behalf of DCF. Please note that foster parents cannot provide consent unless they have a specific delegation of authority from DCF (which is rarely provided). Researcher should also be aware that if DCF has started the court process for removal of parental rights, then DCF will seek court approval prior to allowing the child to be enrolled that may delay obtaining consent to participate.

b) The second method that DCF may be involved with a family is a Child Requiring Assistance (CRA), where DCF is providing general assistance to a family to assist with the care needs of the child. In a CRA, parents retain legal custody and only they can provide the consent for medical decisions and/or enrollment into a research study. The research study does NOT need to obtain an additional consent from DCF.

c) If there is a question as to how DCF is involved with a family for the purposes of obtaining consent to enroll in a study, please contact the BCH Office of General Counsel to review any paperwork regarding DCF involvement.

For children residing in another state who are in state custody of that respective state, the research study can also contact the BCH Office of General Counsel if assistance is needed to review any applicable paperwork from the state agency to determine who can provide consent for enrolling into a research study.

Applying Federal Consent Requirements for Children in State Custody

Utilizing the federal regulations regarding consent requirements children in a research study, the following will be considered by the IRB when enrolling children in state custody (for Massachusetts, this only applies to situations where DCF has a C&P in place) utilizing the risk level criteria outlined in 45 CFR 46.401-409 (which is also duplicated in 21 CFR 50.50–56).

I. Research not involving greater than minimal risk.

There is no greater than minimal risk to children. The IRB only needs to ensure that the study has appropriately obtained the consent of the DCF social worker managing the child's case.

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

There is more than minimal risk to children, but either the intervention or procedure holds the prospect of direct benefit for the individual subject, or a monitoring procedure will likely contribute to the subject's well-being. Then the IRB should determine:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) the study will appropriately obtain the consent of the DCF social worker managing the child's case.

III. Research involving greater than minimal risk and no prospect of direct benefit to individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition.

There is more than minimal risk to children, but the intervention or procedure does not hold out the prospect of direct benefit for the individual subject. The IRB should determine:

(a) The risk represents a minor increase over minimal risk;

(b) The 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;

(c) The 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

(d) the study will appropriately obtain the consent of the DCF social worker managing the child's case.

** Federal requirements also place two specific requirements on children in state custody (again for Massachusetts this is limited to situations where DCF has placed a child in a C&P) participating in research involving greater than minimal risk and no prospect of direct benefit to individual subject:

1. Children in state custody may be included in research that presents greater than minimal risk with no prospect of direct benefit only if the IRB determines and documents that such research is:
    a. Related to their status as wards; or
    b. Conducted in schools, camps, hospital, institutions, or similar settings in which the majority of children involved as participants are not wards
2. If the IRB approves the enrollment in a study per #1 above, then in addition to consent obtained from the DCF social worker managing the child's case, the study will also need to appoint an advocate for any child in the state agency's custody. The advocate must be an individual (in addition to the DCF social worker managing the case) 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. The advocate must not be associated with the research, the investigator(s), or DCF. Advocates may be a member of the IRB or a dedicated person hired to be the central advocate for any research participants within this risk category

As applicable the meeting minutes, reviewer documentation and determination letters will

document the IRB protocol specific findings related to research involving children in state custody.

Procedures

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 in state custody (for Massachusetts those in a C&P with DCF) as potential subjects, and if so whether the investigator plans to offer the study to these children.

1. If the investigator indicates that at the time of protocol application there is a likely possibility that a protocol could involve children in state custody and the investigator wishes to offer the protocol to them, the IRB will make the required federal regulatory findings outlined above.
2. If children in state custody may be included in research where the risk/benefit classification is greater than minimal risk with no prospect of direct benefit, the investigator is responsible for documenting the required findings and the appointment of an advocate.
3. If the investigator does not initially anticipate the inclusion of children in state custody in the protocol, but the circumstances change or a situation arises where the investigators wishes to include them, the IRB office should be contacted. A protocol amendment may be required so that any required regulatory requirements may be fulfilled.
4. When enrolling a child in state custody into a research study, the investigator should make the IRB staff aware of such requests to help determine who needs to provide consent for the child.
5. Investigators should be aware of any changes to the status of a child in state custody, specifically if agencies like DCF changed the status from a C&P to a CRA, by periodically asking the accompanying adult if there has been a change in custody of the child. Note that changes in custody status may require obtaining permission from a new social worker or from a parent/guardian who was awarded custody. In such circumstance, the IRB or BCH Office of General Counsel may be contacted for further guidance.
6. For situations in which children begin a study and then are placed in DCF custody (under a C&P), the original consent still applies and DCF would not need to sign a new consent form – however, the DCF social worker should be aware for continuity of the study. Alternatively, if a child begins a study under DCF custody and the child is later reunited with the parent, the original consent continues to apply – however the parents should also be made aware for continuity of the study.

Because these situations are complex, investigators who wish to enroll children in state custody may want to contact the IRB for guidance in complying with all federal and state regulations pertaining to the inclusion in research.

Document Attributes

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