



# Human Subjects Protection Update

JANUARY 30, 2009

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## **Research Involving Wards of State and Incarcerated Youth**

We are writing to inform and remind investigator's that before you enroll any child who is a ward of the state or an incarcerated youth into a research protocol, you must contact the Clinical Investigation at 57052 or General Counsel at 56800. There are special provisions in the federal and state research regulations that pertain to the participation of children who are considered **wards of the state** or **incarcerated youths**. The inclusion of either group requires that the IRB make special determinations and in some cases the agency responsible for the child also needs to be involved to grant approval.

Recently a Children's investigator did not realize that a child placed in a penal institution under the care of the Department of Youth Services was considered an incarcerated youth and enrolled a subject without the appropriate regulatory findings and approval. As a result we realize we need to better communicate and educate the clinical research community on the definition of wards and incarcerated youth. The following questions and answers provide educational information. Additional detailed information may be found in our policy and procedures at

[http://www.childrenshospital.org/cfapps/research/data\\_admin/Site2206/mainpageS2206P3.html](http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/mainpageS2206P3.html)

### **Who is considered a ward of State?**

A "ward," in this context signifies 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 Division of Children and Families (DCF), previously know as DSS, in the state of Massachusetts.

### **Who is considered an incarcerated youth?**

An incarcerated youth is a child who is in penal custody or otherwise detained within the criminal justice system. These children are under the care of the Department of Youth Services (DYS). These child may be placed in a residential facility and in some cases be placed in a penal institution. In addition some incarcerated youth may also be wards of the state but children can be incarcerated without being a ward.

### **Why do we need to have special procedures and requirements for incarcerated youth and wards involved in research?**

There are separate and distinct human subject regulations for both incarcerated youth and wards of the state. This is based on the vulnerability of these two groups and the special circumstances that surround these children. Children who fit both categories are covered by both regulations. Both sets of regulations require additional IRB determinations, special IRB expertise, and the potential appointment of an ombudsperson. In addition any protocol that involves a ward of state must be additionally reviewed the Massachusetts of Children and Families IRB.

**How do I know if a child is a ward of state or incarcerated?**

Incarcerated youth will always be accompanied by an individual from Division of Youth Services and they will be required to consent to any research. . It may not be immediately obvious that a child is a ward of state. Hints might be the parent identifying them selves as foster parents, the presence of a social or case worker or written information from a social or case worker that is provided during a visit. If you are unsure you may ask the individual who accompanies the child for information regarding their relationship to the child. Also feel free to contact the Office of General Counsel for assistance

**Who is the legal guardian who can provide consent for a ward of state or incarcerated youth?**

The legal guardian may be different for each child. For example when children live in foster homes, the biological parents often maintain the legal authority to consent to their child's medical care and potential involvement in research.. In this situation a foster parent does not have the authority to provide consent for research even if they bring the child into the hospital for visits. In some cases permission to enroll a ward of state into a clinical trial will require a hearing and approval by a judge. For children under the care of DYS, biological parents often retain decision making authority in addition to required consent by DYS. Each case may present a different set of circumstances and therefore it is important to contact the IRB or General Counsel Office for guidance and assistance.

**What happens if a child becomes incarcerated or a ward of state after they are enrolled and have begun the research or they are placed back with a parent or are not longer incarcerated?**

A child's status may change at any time in the research; therefore it is important for the research team to continually monitor the status of a child. If at any time during the course of research, a participant becomes a ward of the state or incarcerated as defined above, you must immediately notify the Committee on Clinical Investigation 57052. At that time, the IRB may need to make the special determinations and contact the Department of Children and Families or Department of Youth Services in order for the child to continue. Any questions about change in status should be referred to Clinical Investigation 57052

**It seems that involvement of a ward of state or incarcerated youth in research is just too difficult and complicated, should I just exclude them from my research?**

No, you should not automatically exclude these children from research. Some research protocols present treatment, therapies or assessments that offer a potential benefit for the child that may only be available through research. To categorically exclude wards or incarcerated youth from research would potentially be unfair and discriminatory. In addition wards and incarcerated youth often have special issues or needs that may be important to consider when performing and analyzing research results. Without their inclusion in research you may miss an important opportunity to gain knowledge about this population and their needs.

**Is there anything I can do to plan ahead for potentially enrolling an incarcerated youth or ward of state?**

Yes, if your protocol has a higher chance of including wards or incarcerated youth based on your eligibility criteria and topic under study, please let the IRB know and fill out the appropriate associated IRB forms with the initial submission. There are some steps that can be taken to gain approval upfront and this will eliminate or reduce the amount of work required if a ward or incarcerated youth becomes eligible. However we also recognize that

most studies do not target these populations and often a ward or incarcerated youth become eligible based on a medical or psychological condition. In these cases please notify the IRB on an individual basis and we will do what we can to move the approval process for these children along, however please realize it may take some time since we may need to coordinate parts of the review and approval with the outside agencies, especially in the case of wards of state.

Please feel free to contact the Clinical Investigation office at 57052 or General Counsel at 56800 with questions or for information at any time.

## **Update on Electronic IRB Review and Submission**

This past summer we began the process of converting to an electronic IRB submission and review process. For the past 6 months we have been developing the electronic submission forms and designing and programming the workflow process. The electronic system will allow PIs to draft, submit and follow their protocol through scientific and departmental review, and then through the IRB approval process including any required ancillary reviews (i.e. Radiation Safety, Clinical Trial, Pharmacy). We already have had coordinators, PIs and IRB members volunteer to view and test the forms and within the next month will begin to meet with others who will be receiving, reviewing and approving the protocols on line. This includes scientific reviewers, department/division signatories, IRB members and all other ancillary reviewers ( pharmacy, the clinical trials office, Radiation Safety, the CTSU etc). The project is broken up into different phases. The first phase and most difficult phase is for new submissions. Other phases will include continuing reviews, amendments and unanticipated problem reporting. When the system goes live all phases will be complete. We expect this to be about a year from now. We need additional volunteers to help us view and test the system. The more we have involved, the more we can receive feedback and modify the system where we can to meet the needs of the research community. This is a "package" software, so not every change is possible, but where we can make changes we will. We have started a list of volunteers and will continue to collect names and contact you. We thank those who already have volunteered. If you are interested please email Susan Kornetsky. We are the process of specifically recruiting volunteers who participate as scientific review and departments chairs and chiefs. We also need more coordinators and PIs for future testing. Please consider volunteering