Research Involving Foster Children (a.k.a. Wards of the State)

Modified: January 2017

Background:

The HHS regulations at 45 CFR part 46, subpart D provide additional protections for children who are also wards of the State or any other agency, institution, or entity. These special protections for wards apply to two categories of research:

1. research approved by an IRB under 45 CFR 46.406; or

2. research approved in accordance with the requirements of 45 CFR 46.407 that requires a special level of HHS review beyond that provided by the Institutional Review Board (IRB).

As set out in 45 CFR 46.409, before children who are wards of the State or any other agency, institution, or entity can be included in either of the two categories of research referenced above, the research must meet the following conditions:

1. the research must be either related to the children’s status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards; and

2. the IRB must require appointment of an advocate for each child who is a ward, 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, and must be an individual 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 should represent the individual child subject’s interests throughout the child’s participation in the research. The HHS regulations further require that the advocate 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.

Q: Are there any state requirements for research involving foster children?

Children who are wards of the State of Florida may be included in research, however, the Department of Children and Families (DCF) has additional requirements for research involving “all Department and contracted provider staff that engage in, plan to engage in, or are asked to authorize or support research using human subjects within DCF’s area of responsibility.”

DCF requires that any person or entity who wants to conduct research involving individuals who are receiving services from, or on behalf of, DCF, or involves DCF employees, have written approval from a designated IRB and must provide a copy of that approval notification to DCF’s Human Protections Administrator. UF’s IRBs -01, -02, and -03 are designated IRBs.

In addition to IRB approval, the investigator must have DCF approval to conduct the human subject research. DCF advises investigators obtain DCF approval prior to proceeding with IRB review.
For information on DCF’s approval process, please see their policy, CF Operating Procedure No. 215-8. [Link to https://www.dcf.state.fl.us/admin/publications/cfops/CFOP%20215-xx%20Safety/CFOP%20215-8,%20Institutional%20Oversight%20of%20Human%20Subject%20Research%20and%20Institutional%20Review%20Board%20Designation.pdf]