Appendix 3
Wards

The Department of Health and Human Services (HHS) regulations at 45 CFR 46, subpart D and FDA's regulations at 21 CFR 50, 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 Institutional Review Board (IRB)/Ethics Committee (EC) under 45 CFR §46.406 or 21 CFR §50.53;

   OR

2. research approved in accordance with the requirements of 45 CFR §46.407 or 21 CFR §50.54 .

Wards can only participate in these studies if the IRB/EC ensures the following conditions are met:

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/EC 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.

IRB/EC Appointment of Advocates

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 HHS regulations at 45 CFR §46.409 and the FDA regulations at 21 CFR §50.56 further require that the advocate not be associated in any way (except in the role as advocate or member of the IRB/EC) with the research, the investigator(s), or the guardian organization.

ARCHIVED POLICY
NOT ACTIVE