Standard Operating Procedure For:
Legal Guardianship of Study Subjects

Developed by: **Maureen Famigletti,** Division of Pediatric Infectious Disease
Regina McGraw, University Counsel's Office

Purpose

The purpose of this standard operating procedure (SOP) is to provide a plan and guidance for research personnel to confirm and track legal guardianship of pediatric research subjects in order to ensure that documentation of consent to participate in research is executed legally.

Scope

This SOP is based upon: 1) the DHHS Code of Federal Regulations (45 CFR 46), 2) New York State laws governing legal guardianship of minors and 3) SUNY Upstate Medical University IRB policy. This SOP applies to all minor subjects enrolled in clinical trials through the Division of Pediatric Infectious Disease at SUNY Upstate Medical University.

Guardian **means any person or authorized agency to whom letters of guardianship have been issued by a court provided the guardian is granted the authority to consent to medical care and treatment on behalf of the minor.**

Plan

Each subject being considered for study participation will have guardianship status identified. If the subject is not in the custodial care of a biological parent, documentation will be placed in the permanent medical record of their custody status. At each visit, the clinician will review custody status; any change in status will be noted in the clinical record with appropriate documentation as needed.

Each protocol reviewed and approved by the IRB receives a risk/benefit category assignment as per CFR 45 Part 46, Subpart D:

- 45 CFR §46.404, Research not involving greater than minimal risk
- 45 CFR §46.405, Research involving greater than minimal risk but presenting the prospects of direct benefit to the individual subjects.
- 45 CFR §46.406, Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- 45 CFR §46.407, Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

In addition to the above determination, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian.

Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Documentation of consent for study participation by minors will be obtained as follows:

- Children in the care and custody of their biological parent(s) will have consent documents signed by their parent(s) for any category study.
- Children living with other family members will, if circumstances permit, have consent documents signed by their biological parent(s) whenever possible for any category. If the parent(s) is not available , the child will not be able to participate in clinical research unless custody is awarded through a court decision as defined above.
- Children in the custody of the Department of Social Services (DSS) will have consent documents signed by the legally authorized DSS official for any category study. . **If the research is approved under category** §46.406 or §46.407**, the IRB shall 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. The advocate shall 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 and who is not 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.**