1. **PURPOSE:** To provide additional protection for children who are wards of the state or foster children when they participate in research.

2. **POLICY:** The investigator must obtain the permission of a legally authorized representative (LAR) before including a child who is a ward of the state or any other agency, institution, or entity.

   2.1. When the specific research under review involves either minimal risk or more than minimal risk with the prospect of direct benefit to the individual participants [45CFR 46.404 or 405] [21CFR50.51 or 52], the IRB and Investigator will follow the standard procedures for IRB Research Involving Children, Parental Permission and Assent.

   2.2. For all other research, e.g., research that involves more than a minor increase with no prospect of direct benefit, or research that requires review and approval by DHSS or FDA [45CFR 46.406 or 407] [21CFR50.53 or 54], in addition to the standard procedures for IRB Research Involving Children, Parental Permission and Assent, the IRB will approve the inclusion of wards or foster children only if:

   2.2.1. An advocate is appointed for each ward or foster child in addition to any other individual acting on behalf of the child as guardian or in loco parentis; and

   2.2.2. Either of the following apply:

       - The research is related to the child’s status as a ward or foster child; or
       - The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

3. **DEFINITIONS:** A glossary of terms and concepts found in the Nemours HSP policies and procedures is located on the NOHSP website.

   3.1. **Ward:** A child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

   3.2. **Foster Child:** A ward who is in the temporary care of a family other than its own under some kind of short-term or long-term foster care arrangement with the custodial agency.

   3.3. **Advocate:** 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. One individual may serve as advocate for more than one child.
This includes ensuring that to the extent possible, the child understands what will be required of him or her during the research, and that if capable, the child provides his or her assent to participate. Acting in the best interests of the child could include evaluating the ongoing impact of the research study on the child. The advocate should represent the individual child subject's interests throughout the child's participation in the research. This added protection is intended to ensure that the ward, who is particularly vulnerable, is not exploited, coerced, or subjected to undue influence or harm in the course of the research.

3.4. Child: Persons (who may or may not be minors) who have not attained the legal status for to consent to treatments or procedures involved in research (clinical investigations), under the applicable law of the jurisdiction in which the research will be conducted.

3.5. Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Individuals who meet this definition, but are not parents and do not meet the DHHS and FDA definition of guardian (are not authorized under applicable law to consent on behalf of the child to general medical care) may not grant permission for a child to take part in research.

3.6. Legal Guardian: A person who has the authority to consent on behalf of the child to general medical care.

- Note that individuals who are designated as a “legal guardian” under state law, such as foster parents, may not have the authority to consent for a child’s general medical care and therefore cannot consent on behalf of the child to this research.
- Note that individuals who are not designated as a “legal guardian” under state law, such as social service case worker, may have the authority consent for a child’s general medical care and therefore can consent on behalf of the child to this research.

4. PROCEDURES:

IRB review:

4.1. The IRB review and approval process will be conducted according to all applicable policies (referenced below).

4.2. In addition to determining whether all approval criteria are met, the IRB will assure that:

4.2.1. Inclusion of wards or foster children is justified by the research design.

4.2.2. Recruitment and enrollment procedures are in compliance with this policy.

Child Advocate

4.3. The investigator will assure that the process for obtaining an advocate for the duration of the study is adequate and is compliant with state law.

4.4. To obtain an advocate, the investigator may work with a caseworker, social worker, or counselor responsible for the child’s rights and welfare.

4.5. The IRB will review the advocate(s)’ qualification to assure that:

4.5.1. The advocate is not associated with the research.

4.5.2. The advocate will be available for the duration of the research, or that a system is in place that assures continuity if there is a need to change advocates during the research.

4.5.3. The advocate has the ability to protect the child’s rights as a research participant.

4.6. The IRB will obtain a review of the advocacy process by the IRB’s legal representative before approving the research.
4.7. **Parental Permission and Assent:** The investigator or designee conducting the permission and assent process will follow all applicable IRB policies (referenced below).

4.8. **Change in status while enrolled in research that is more than minimal risk:** If there is a change in the child’s legal status after enrollment, e.g., no longer a ward or a foster child, or becoming a ward or foster child, the investigator will suspend all research activities for the affected participant, except for those necessary to the safety of the participant, until permission has been obtained from the current LAR.

4.9. The investigator will report any change in the child’s legal status to the IRB Chair as soon as he or she becomes aware of the change.

4.9.1. A change in foster parents does not require a new consent provided that the state remains the legal guardian.

5. **REGULATORY / GUIDANCE REFERENCES:**

5.1. [45 CFR 46.409, 21CFR50.56](#) Wards

5.2. [45CFR46, 21CFR50 Subpart D](#) Additional Safeguards for Children in Research/Clinical Investigations

5.3. [HSP-029 IRB Review Basics, HSP-027 Review of Research Involving Children, HSP-043 Parental Permission, HSP-033 Assent](#)

5.4. Nemours Standard Business Process related to [Documentation of Guardianship](#). (accessible through Nemours Intranet only).

6. **AAHRPP STANDARD REFERENCES:** II.4.C The Research Review Unit has and follows written policies and procedures for determining the risks to vulnerable populations as defined in applicable federal regulations, and specifically for determining the required risk categories in protocols involving children and prisoners.