Considerations for Research Involving Children

References: IRB Policy 17.1, *Children in Research*
OHRP *Research with Children FAQs*

Category of Research: The IRB must determine which category, in terms of risks and benefits, the study falls into.

☐ **Category 1** – The research poses no greater than minimal risk

☐ **Category 2** – The research poses greater than minimal risk but presents the prospect of direct benefit to the individual subjects.

☐ **Category 3** – 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 condition or disorder.

Note: Research involving children can have two risk categories. For example, in a study involving a test article and a placebo, the intervention group may be Category 2 and the placebo group Category 3.

Assent – Generally required for children ages 7 and up. Consider which of the following applies to the research.

☐ **Assent required**: The children are capable of providing assent, given their ages, maturity, and psychological state.

☐ **Assent not required**: The capability of some or all of the children is so limited that they cannot reasonably be consulted. Typically because of age or cognitive level.

☐ **Assent obtainable but a child's refusal can be overridden or assent can be waived**: The intervention or procedure holds out a prospect of direct benefit that is important to the health or well-being of the children AND is available only in the context of the research.

Assent can be documented on a separate assent form, or as part of the parental permission form. Study teams can also have different assent documentations targeted to particular age groups.

Parental Permission – Regulations require two signatures on a parental permission (consent) form. However, the IRB can determine a single parent's signature suffices in certain conditions.

☐ **One parent signature** -- Usually applicable to Category 1 or Category 2 only. However, for studies that are NOT subject to the Common Rule (i.e. not federally funded or supported) and NOT FDA regulated, the IRB can consider requiring only one parent signature for Category 3 research.

☐ **Both parents' signatures required** unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the child -- Typically for Category 3 studies.