Determinations for Children

**Category A**
- Research involves NO MORE than minimal risk
- Adequate provisions are made for obtaining the child’s assent (> 6 years) and the permission of parents or guardians
  - Child’s assent & permission of one parent is sufficient
    - Study cannot be approved as written
  - CATEGORY A

**Category B**
- Research involves GREATER than minimal risk
- The research presents the prospect of direct benefit for participants
  - Child’s assent & permission of one parent is sufficient
    - Study cannot be approved as written
  - CATEGORY B

**Category C**
- Research involves GREATER than minimal risk
  - The research presents NO prospect of direct benefit for participants
    - CATEGORY B

**Category D**
- Research not otherwise approvable in Categories A-C
  - The child’s assent and permission of both parents is required (unless one is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)
    - CATEGORY D

The research presents the prospect of direct benefit for participants
- The risks are justified by the anticipated benefits, which are at least as favorable as an alternative approach.
- Adequate provisions are made for obtaining the child’s assent (> 6 years) and the permission of parents or guardians
  - Child’s assent & permission of one parent is sufficient
    - Study cannot be approved as written
  - CATEGORY B

The research presents the child with experiences that are reasonably commensurate with those in the child’s actual or expected medical, psychological, social, or educational situations
- The research will likely yield generalizable knowledge about the child’s condition that is of vital importance to an understanding or amelioration of the condition
- Adequate provisions are made for obtaining the child’s assent (> 6 years) and the permission of parents or guardians
  - Study cannot be approved as written
  - CATEGORY C

The child’s assent and permission of both parents is required (unless one is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)
- Adequate provisions are made for obtaining the child’s assent (> 6 years) & permission of parents or guardians
  - Study cannot be approved as written
  - CATEGORY D

APPROVED BY SECRETARY OF DHHS

The child’s assent and permission of both parents is required (unless one is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)