

Rev. 07/12

ASSENT BY CHILD SUBJECTS

POLICY:

All child subjects are to be given a clear and complete picture of the research in which they are asked to participate, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand.

PROCEDURES:

All children from 10 to 17 years of age are required to give written assent. Children less than 10 years of age and all individuals, regardless of age, with delayed cognitive functioning (or with communication skills that make expressive responses unreliable) will be denied involvement in any research that does not provide a benefit/risk advantage. Good faith efforts will be made to assess the actual level of competence of child subjects where it is in doubt.

Parental permission is required for children ages birth through 9 years. The IRB proposal must clearly describe acceptable procedures for informing the child subjects of the nature of the research and of its risks and benefits, as well as how the level of competence to understand and assent will be ascertained.

For children from 10 to 17 years, parental permission and a separate Assent Form are required. Exceptions will be made if the subject is an emancipated minor, per The State of Montana's statutory definitions. The IRB proposal must clearly describe acceptable procedures for informing the child subjects of the nature of the research and of its risks and benefits, as well as how the level of competence to understand and assent will be ascertained.

Waiver of a child subject's informed assent should be limited to situations where the study offers clear promise of benefit through a treatment that is not available outside the research setting. When a waiver is appropriate, there is a clear expectation that the child subject will be informed of the risks and benefits of the treatment.

Parental permission (in addition to the child's assent, as outlined above) is required for all survey research, unless the investigator can make a compelling argument to the contrary. When research takes place within a school district, school officials must agree to the waiver of parental permission. Exceptions to the waiver policy will be considered if parental permission would be unavailable (e.g., parental abuse or neglect) and if the information about the child subject could be used in the interests of the child.