SOP 1.4.1 **Research Involving Children**

General Description:

Research activities at GMU involving humans must undergo some level of ethical review by the IRB office or the IRB. Per the federal regulations, at 45 CFR 46, children are considered a vulnerable population and research involving children as participants requires additional considerations or protections.

Children are defined in the regulations as individuals who have not attained the legal age for consent to treatment or procedures involved in the research (within the jurisdiction in which the research will be conducted).

Policy:

1. Children may be involved in research in many of the exempt categories with a few exceptions. See 45 CFR 46.104(b)(3).
2. For non-exempt research involving children, the IRB applies 45 CFR 46 Subpart D to studies. Under Subpart D, the IRB is allowed to approve three types of research:
    a. Research that does not involve greater than minimal risk to the children (minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
    b. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.
    c. Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.
3. One or both parents (or a guardian) must provide and document permission for a child to participate in research (as noted below), unless these requirements are waived by the IRB. In most cases, children capable of assent must also express their willingness to participate.

Regulatory Category of Permitted Research with Children	**One Parent's or Both Parents' Permission Required?**
Minimal Risk (45 CFR 46.404, 21 CFR 50.51)	**One parent**/legal guardian *may* be sufficient
Greater than Minimal Risk, Direct Benefit to Subject (45 CFR 46.405 21 CFR 50.52)	**One parent**/legal guardian *may* be sufficient but IRB must determine whether one or two is required
Greater than Minimal Risk, No Direct Benefit to Subject, but Likely to Yield Generalizable Knowledge about Subject's Condition (45 CFR 46.406 21 CFR 50.53)	**Both parents**/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
Greater than Minimal Risk, No Direct Benefit to Subject, but Results May Alleviate Serious Problems of Children's Health or Welfare (45 CFR 46.407 21 CFR 50.54)	**Both parents**/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.

4. FDA regulated research involving children must comply with the requirements of 21 CFR 50, Subpart D and 21 CFR 56.
5. Parental permission may not be waived for research involving children that is covered by the FDA regulations.

6. Additional protections are in place for children who are wards of the state: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.409.

Procedures:

1. If a research project involves children as participants, researchers must include this information in the applicable sections of the IRB application and complete Addendum A (Minors) describing the recruitment and consent process for both parents and children.
2. If the research includes enrollment of children in other countries, the researcher should indicate the age of majority (adult status) in the country where the research will be conducted and provide any other relevant information.
3. Template assent forms are available in IRBNet for different age groups of children. The language in the consent form template may be altered such that it is appropriate for parents to provide consent for their child to participate.
4. The IRB will review the protocol in accordance with 45 CFR 46 Subpart D. The checklist for research involving children will be completed by the IRB which will ensure that regulatory requirements for research involving children have been met including any discussion of research that falls into category 45 CFR 46.407.
5. The IRB will determine that the researcher describes adequate provisions for soliciting the permission of parents or guardians or that a waiver of parental consent or child assent is appropriate and justified based on the regulations.
6. The IRB will follow regular procedures for an exempt, expedited or full board review as necessary.

Related Forms, Guidance, and SOPs:

- 45 CFR 46 Subpart D
- http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/
- 21 CFR 50 Subpart D
- IRB application addendum A -- Minors
- 2.2.1 Informed consent, assent, parental permission, and documentation
- 2.5.1 Full board review
- 2.5.2 Exempt and expedited

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

Date First Effective:	February 22, 2017
Revision Date:	[DATE]
Current Version #:	1

Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	February 22, 2017
Laurie Meamber	IRB Chairperson	February 22, 2017