 <p>MARQUETTE UNIVERSITY Office of Research Compliance</p>	SOP	Title	Date	Page
	IRB-500	Human Subject Populations	July 2018	1 of 2

1. PURPOSE

1.1. This policy establishes the process for reviewing research protocols involving vulnerable populations; fetuses, pregnant women, or human in vitro fertilization; prisoners; and children.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Vulnerable Populations:


3.1.1. Vulnerable populations may include women, human fetuses, neonates, prisoners, children, persons with physical handicaps or mental disabilities, and persons who are disadvantaged economically or educationally. Additionally, vulnerable populations may include racial minorities, the very sick, and the institutionalized.

3.2. IRB Review of Research Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization:

3.2.1. When the proposed research involves fetuses, pregnant women, or human in vitro fertilization, the IRB considers the additional protections outlined in Subpart B, of 45 C.F.R. § 46. In addition, the IRB will only review research involving fetuses, pregnant women, and human in vitro fertilization when there is at least one member present who is uniquely qualified by their experience and training to review and approve the research. The IRB's discussions, findings, and determinations are documented in the IRB meeting minutes for each specific research protocol.

3.3. IRB Review of Research Involving Prisoners:

3.3.1. When the proposed research involves prisoners, the IRB considers the additional protections outlined in Subpart C of 45 C.F.R. § 46. In addition, the IRB will only review research involving prisoners when there are members present who are uniquely qualified by their experience and training to represent the interests of prisoners in the review and approval of this research. The MU IRB has a member who has the appropriate background and experience to serve as a Prisoner Representative. This member only counts toward quorum when he or she is present and reviewing studies covered by subpart C. The IRB's discussion, findings and decisions in regard to the

	SOP	Title	Date	Page
	IRB-500	Human Subject Populations	July 2018	2 of 2

requirements of 45 C.F.R. § 46.305 and 45 C.F.R. § 46.306 are documented in the IRB meeting minutes.

3.4. IRB Review of Research Involving Children:

3.4.1. When the proposed research involves children, the IRB considers the additional protections and the parental permission and assent procedures outlined in Subpart D of 45 C.F.R. § 46. The IRB discussion, findings and determinations in regard to the requirements of 45 C.F.R. § 46.404 through 45 C.F.R. § 46.408 are documented in the IRB meeting minutes. The ORC provides IRB reviewers with a checklist titled, “IRB Review of Protocols Involving Children.” For any protocol involving children, the IRB must determine which of the categories of research apply to that study, if any, and provide the rationale.

3.5. Assent for Minors:

3.5.1. In the State of Wisconsin, only individuals 18 years or older may legally consent to participate in research. Individuals who do not have this authority to consent must still provide assent. “Assent” is an active affirmation to participate in a research study. If the individual giving assent is able to read and write, then assent should be documented using the IRB Assent template; otherwise, assent should be obtained through dialogue with the subject. The assent discussion and form should be in language understandable to the subject and contain the same elements as those stated under “Informed Consent Process and Documentation.” For further information regarding Assent for Minors including a Parental Permission Template and Assent Template, see the ORC website.