Grand Valley State University Institutional Review Board (IRB)	
Title: *Protections for pregnant women, fetuses, and neonates*	
Section: 721	This policy and procedure supersedes those previously drafted
Approved by HRRPPC: 11/28/2017	Approved by the AIO/RIO: 04/16/2018 Approved by the AIO/RIO: 03/16/2020
Effective Date: 01/21/2019	
Related documents: 710: *Assessing risk to research participants* *720: Assessing risk to vulnerable participants* *730: Collection, management and security of research information* *G-1: Guidance on research involving vulnerable populations* *G-5: Guidance on assessing risk using magnitude of harm in categorizing risk level* *G-6: SACHRPP guidance on assessing risk*	

Policy

Special considerations must be taken when participants of research are pregnant women if the research-related risks to the participants are correlated to the medical condition of being pregnant.

Procedures

1. Researchers should review the guidance provided in 45 CFR 46.204 and 45 CFR 46.205 concerning pregnant women, fetuses, and neonates.

2. Researchers should specify measures to minimize risks for pregnant women and their fetuses in protocols and informed consent documents, if appropriate.

Additional Guidance

1. Special considerations for pregnant women

   Research-related risks to this population are those that are directly or indirectly connected to the medical condition of being pregnant. Taking a survey about personal career interests is a minimal risk activity for anyone, including pregnant persons. Taking a new medication for acne may be minimal risk for non-pregnant adults but greater than minimal risk for pregnant adults because it is unknown what effects the medication may have on the woman's fetus.

2. Example of a study requiring additional considerations for pregnant women

   Question: How should a study that involves pregnant women walking a mile without resting be classified as to risk?

   Response: A research procedure or intervention may pose greater than minimal risk to some individuals but not to others. For example, walking for a mile without resting may be greater than minimal risk for persons with breathing problems, but minimal risk for those without such problems. In such cases, the assessment of risk assigned to the overall study is that which is appropriate for the most members of the target population. Thus, such a study would be classified as greater than minimal risk if it is reasonable to presume that at least some participants are likely

to have or to develop breathing problems even if they have not been previously diagnosed with breathing problems, and even if no participant actually develops such problems in the study.

On the other hand, if all potential participants are initially screened for breathing and other problems, and all are determined to be in very good or excellent health, the study may be assessed as minimal risk for the population under study. Thus, if the pregnant participants are screened for hypertension and breathing problems before participating, the study may be classified as minimal risk.