

Grand Valley State University Human Research Review Committee Procedure	
Subject: Review of Protocols Involving Research on Vulnerable Populations	
Section: 20	This procedure supersedes those previously drafted
Initially adopted as procedure on January 15, 2008	<i>Approved by:</i> Dean of Graduate Studies and Grants Administration, on
Related Sections: procedures 16, 17	

Research protocols that involve vulnerable populations but contain no greater than minimal risk to enrolled subjects and otherwise qualify for expedited review shall be reviewed using expedited review procedures.

The exception to this procedure is that all research involving prisoners as defined by the federal regulations and interpreted under OHRP guidance shall require full board review.

Vulnerable populations include but are not limited to the following categories of research subjects.

- A. Pregnant women, neonates and fetuses
- B. Minors
- C. Cognitively or decisionally impaired persons

Consent and assent requirements and related documentation thereof for research subjects in vulnerable populations shall be made in accord with the research subjects' best interests and in compliance with all applicable federal regulations and OHRP guidance.