

 MARQUETTE UNIVERSITY Office of Research Compliance	SOP	Title	Date	Page
	IRB-410	Greater Than Minor Modifications	July 2018	1 of 1

1. PURPOSE

1.1. This policy establishes the submission and review process for previously approved protocols under expedited or convened IRB requesting greater than minor modifications.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Proposed amendments which including greater than minor modifications to an approved project are reviewed by the full board IRB at one of its regularly scheduled meetings. The IRB makes one of the following determinations:

- (1) **Approved** as written.
- (2) **Approved with Contingencies**, modifications are required to secure approval.
- (3) **Table** for further review at a subsequent full board IRB meeting.
- (4) **Disapprove**: Modification cannot be implemented.

3.2. The decisions are based on the votes of the majority (more than 50%) of the voting members present at a full board IRB meeting. IRB members are requested to ensure all criteria for continuing review are considered, met, and documented. This also includes the information about the results of the review that the ORC will communicate, in writing, to the PI.

3.3. The date of approval of an amendment does not change the original approval period or the expiration date (if applicable) by which the regularly scheduled continuing review of the research project should be done unless the amendment increases the risk to benefit ratio, thus warranting the study to be reviewed more frequently.