

 MARQUETTE UNIVERSITY <small>Office of Research Compliance</small>				
	IRB-400	Minor Modifications	July 2018	1 of 2

1. PURPOSE

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

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. The IRB may review minor changes in previously approved research during the period for which approval has been given, under expedited review procedures (45 C.F.R. § 46.110 and 21 C.F.R. § 56.110). A is a change in approved research that can be approved through expedited review procedures that neither materially increase risk, nor materially decrease benefit, nor materially decrease scientific merit. If the change is not considered it must be reviewed by the full board IRB at a convened meeting.

3.2. Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. The IRB Chair or experienced IRB members review the amendment, after a pre-review by ORC, to ensure all criteria for review are considered, met, and documented.

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