

 MARQUETTE UNIVERSITY Office of Research Compliance	SOP	Title	Date	Page
	IRB-420	Modifications to Exempt Protocols	July 2018	1 of 1

1. PURPOSE

1.1. This policy establishes the submission and review process for protocols given exempt status requesting modifications.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. If a protocol was originally deemed exempt, then a formal amendment is not required as long as the change does not affect participant risk. Instead, researchers should submit a detailed explanation via email, describing the proposed changes and identifying the PI, study title, and MU IRB protocol number.

3.2. Researchers should wait for verification from the ORC that the proposed changes do not affect participant risk. If a change to an exempt protocol does affect participant risk, the ORC may instruct the PI to submit an amendment and/or complete a new IRB application for review and approval before being initiated, except when necessary to eliminate apparent immediate hazards to the human subjects.

3.3. Changes to exempt protocols that may affect participant risk:

- Collecting identifiable private information
- Adding procedures that are deemed minimal risk or more than minimal risk

3.4. Changes to exempt protocols that usually do not affect participant risk:

- Increase in number of subjects for recruitment
- Adding non-key personnel, such as personnel who will hand out anonymous surveys or analyze de-identified data