

Amending your human subjects research protocol

Any changes to **expedited** or **full-review protocols** must be requested in writing by submitting an IRB Protocol Amendment Form (<http://www.marquette.edu/researchcompliance/research/irbforms.shtml>). All changes must undergo IRB review and approval before being initiated, except when necessary to eliminate apparent immediate hazards to the human subjects.

Changes to **expedited** and **full-review protocols** that require an amendment include, but are not limited to:

- Change in procedure
- Change in research location
- Change in key research personnel
- Change to consent form
- Change to advertisement
- Increase in number of subjects to be recruited

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 and protocol number. 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 PI must submit an amendment and the change must undergo IRB review and approval before being initiated, except when necessary to eliminate apparent immediate hazards to the human subjects.

Changes to **exempt protocols** that affect participant risk:

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

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

Researchers should review approval letters to confirm whether a protocol was **exempt, expedited, or full review**, as the category is determined by the IRB. Contact the ORC with questions about making any changes to an approved human subjects protocol.

Refer to Marquette University's Human Research Protection Policy Number 98.104 for information about protocol deviations and non-compliance.