New procedure for reviewing applications to conduct exempt research

The procedure for reviewing applications to conduct exempt research has been changed to increase efficiency and reduce administrative burden on IRB staff. It is not anticipated that the changes will affect participant safety.

The following changes are effective immediately:

- 1. An application file will be closed as soon as a determination of exemption is made.
- 2. The investigator is not required to close a project or file an end of project report.
- 3. Projects can no longer be amended.
- (a) <u>Minor changes</u> such as changes in wording of the consent form or changes in non-key personnel (eg, research assistants) can be made by investigators without approval from the IRB. Investigators are advised to maintain their own records of changes they make.
- (b) <u>Major changes</u> such as a new principal investigator or co-investigator; changes in methodology; or changes in compensation to participants will require a <u>new</u> application.

What has not changed

The following must be reported immediately to the IRB: Any injuries to research participants or any events that increase the risk to research participants.

rsb: 6/11/20