

- < Research Protocol, Investigator brochure, or device specifications (where applicable)
- < Questionnaires & assessment instruments, plus copies of these documents translated to the appropriate local language.
- < Proposed informed consent document(s); plus, copies of these documents translated to the appropriate local language

Requirements:

1. Cover letter requesting for approval of the amendment and a description of the changes proposed indicating the rationale.
2. Submit 03 copies of the previously approved protocol, study instruments and consent forms.
3. 03 copies of the amended protocol, study instruments and consent forms with track changes (highlighting proposed changes) should also be submitted
4. The Investigator pays \$200 to accounts Officer and brings the photocopy of the receipt when submitting the documents.

E. Requirements for Expedited Review of a Protocol

An expedited review, refers to review of a proposal in the quickest way possible, there's no requirement for a meeting, the chairman can either review the submitted proposal or assign it to any other designated MU-IRB reviewer (s), the P.I should expect to get IRB comments within a week which they have to respond to before approval is granted. However not all studies can fit the criteria for expedited review, the MU-IRB chairman and Administrator have to review the proposal in line with the MU-IRB SOPs to determine if it meets the criteria for expedited review.

List of requirements:

1. A cover letter addressed to the IRB Chairman requesting for expedited review, explaining why you think the study qualifies for expedited review.
2. A submission form should be attached to (03) copies of the proposal to be submitted for review.
3. The Investigator should wait to hear from the Committee confirming to them if their study qualifies for expedited review, (the Investigator can be notified within 3 days)
4. The Investigator pays the fees (refer to fees structure) to accounts Officer and brings the Photocopy of the receipt when submitting the documents. Or through bank account after getting clearance from IRB Administrator.

F. Requirements for Exemption from IRB Review

Requests for exemption are also reviewed expeditiously and only apply to proposals which don't involve human subjects, studies that only employ document review and many other specifications in the SOP (Send summary of proposed study).

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