



NATIONAL COMMITTEE ON RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES (NCRSH)

SOP NO.4: Standard Operating Procedure for Expedited Review

Purpose

This SOP describes the process of approval of studies with minimal risk; minimal risk changes or modifications/amendments required by NCRSH; or minimal risk investigator-initiated clarifications, modifications/amendments to a previously approved protocol and related documents so as to prevent unnecessary delays in reviewing them. The SOP also describes the approval process of studies by researchers and students so long as such studies are of minimal risk.

Scope

Expedited review applies to protocols, letters of clarifications, and letters of amendments, informed consent forms and community awareness materials. The SOP applies to NCRSH members, Chairperson and secretariat.

It is the responsibility of NCRSH secretariat to determine which study protocols should be reviewed and approved through expedited process as long as such determination is within the standards described under the purpose section above.

Allowable Exceptions

This SOP is meant to be followed without deviation

Specific Procedure

- Following the administrative screening as per **SOP No.2**, secretariat and chairperson appoint three reviewers to undertake the expedited review
- The reviewers independently review the submitted protocol and/or materials described under the scope section above.

- In case of a protocol, the reviewers assess the protocol by using the protocol assessment form and send the completed forms and their recommendations to secretariat within **14 days**
 - In case of review of non protocol materials, reviewers review them and send their written opinion/recommendations to the secretariat within 14 days
 - The Chairperson and secretariat confer to make a decision basing on the recommendations from the reviewers. If one reviewer expresses a strong deferring opinion, the review of the protocol would be referred to the full committee review and decision would be made basing on **SOP No.3** where circumstantial referral to a relevant authority may be sought.
 - The secretariat issues a letter to communicate the decision of the expedited review within seven days after receipt of completed assessment forms and written opinion/recommendations from the reviewers.
 - The chairperson reports to the committee for ratification at the next meeting
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Definition of Terms

Expedited review: A review process by only two or three designated NCRSH members who then report the decision to the secretariat and chairperson where the latter reports to the full committee meeting for ratification. An expedited review is a speedy review process for protocol of minimal risk including those of students and is also a review process of minor changes to the originally approved protocol with minimal risk in nature and/or for minor requests.

Expedited approval: NCRSH approval granted only by the chairperson of NCRSH made in conferring with the secretariat basing on the reviews and recommendations of two or three reviewers of a protocol of minimal risk or of minor changes to the previously approved research studies of minimal risk.

Minimal risk: risk that entails a situation where probability and magnitude of harm or discomfort anticipated in the research is not greater than that which is ordinarily encountered in daily life (i.e. probability and magnitude of harm or discomfort that is not anticipated to affect the safety, physical or mental integrity of the study participants).

Minor modifications/changes: administrative revisions, such as correction of typos and clarifications