



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

SOP NO.8: Standard Operating Procedure for Inspection of Approved Protocols

Purpose

This SOP describes how inspection of studies approved by NCRSH will be conducted

Scope

The usage of this SOP applies to NCRSH members, secretariat, investigators and study staff

Allowable Exceptions

This SOP is meant to be followed without deviation

Specific Procedure

- NCRSH shall inspect approved studies through the following mechanisms;
 - Progress report submitted once midway of the study implementation, if study is to be completed within one year
 - Final report submitted at the end of the study
 - Progress report every half yearly, annual report and final report, if study takes more than one year
 - Inspection reports by specially appointed NCRSH sub-committee carrying out inspection visits
 - Where possible, copies of publications at the end of the study
- Investigator submits annual and progress reports as described above in a format that shall be specified by NCRSH (ie NCRSH shall have a form for use by investigators in submitting the required reports)

- In case of inspections reports, NCRSH inspections sub-committee shall submit inspections report to the committee
 - NCRSH reviews report and make recommendations through either expedited or convened full committee review process
 - Chairperson and secretariat communicate recommendations/feedback of review of reports to investigator
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Definition of Terms

Inspection: An action that NCRSH or its sub-committee or its representatives visit the study sites to assess how well the investigators and the sites are **complying** with the approved protocol and applicable regulatory, and ethical requirements. Normally, inspection visits will be arranged in advance with the Principal Investigator but NCRSH may also conduct unannounced visits.