

How to Submit a Protocol for Ethical Review – Documents & Reporting Requirements

By

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Introduction

- Research ethics committees are set up to protect potential participants in research & research community, investigators, & also the host institution
- The committee is structured & equipped to function in such a way to ensure that researchers comply with all it takes to conduct scientifically & ethically valid studies

Introduction

- The activities of the committee should be well organized with adequate documentation of processes and outcome of meetings
- Additionally, research proposals received from investigators should be written in such a way that the content and process of the proposed research are clearly highlighted to give the committee adequate information
- A review of this (protocol) will assist the committee in deciding whether the proposal is approved for modification or rejected.

Introduction

- Realizing these demands that the day to day running of ethics committees, & their processes should facilitate the realization of this objective
- Proposals sent by researchers should meet certain minimum requirements in line with local, national, & international guidelines.

Introduction

- This presentation focuses on the reports and records to be kept by ethics committees as well as the requirements for submitting protocols to ethics committees by researchers
 - The contents of Section K of the National Code for Health Research forms the guide.

Requirements for Submission of Protocol

Submission of:

- Copy of the research proposal
- Copy of all materials to be used for the consent process such as consent forms and advertisements, including but not limited to promotional materials, advertisements, notices in newspapers, trade publications, audio, video and web advertisements.

Requirements for Submission of Protocol

- Copy of brief curriculum vitae (2 – 3 pages) of the principal investigator(s) sufficient to judge ability to carry out the proposed research.
- Copy of letter(s) of support from co-investigator(s), laboratories and sources of required resources.
- Where applicable, letter of sponsorship.
- One page plain language summary of the research.

Requirements for Submission of Protocol

- Copies of all questionnaires and instruments to be used for the study.
- Other ethics committee(s)' review of the study and their decisions, where applicable.
- Evidence of NHREC certified informed consent training by applicant and co-investigator(s) undertaken within 2 years of the date of submission of a valid application to HREC
- Copies of all agreements such as the MTA etc. where indicated.

Requirements for Submission of Protocol

- Investigator(s) must submit an annual report on their research to HREC within 3 months of expiry of their current research approval.

Requirements for Submission of Protocol

- This report shall contain
 - ✓ brief summary statistics about the research
 - ✓ number of participants recruited and their breakdown,
 - ✓ number of adverse events,
 - ✓ complaints and their resolution,
 - ✓ any ongoing investigation or review and copies of any publications,
 - ✓ reports or abstracts arising from the research.

Requirements for Submission of Protocol

- Failure to submit annual report within the stipulated period shall lead to termination of research by HREC.
- HREC may issue letters of notification advising researchers of the need to submit annual reports.

Requirements for Submission of Protocol

- HREC shall determine the form and number of copies of materials to be submitted by applicants for research review.
- All HREC records shall be accessible for inspection and copying by NHREC and through NHREC by other agencies at the discretion of NHREC and in a reasonable manner.

HREC Records & Reports

- HREC shall prepare & maintain adequate documentation of all its activities, including:
 - All materials pertinent to research review such as:
 - ✓ Copies of all research proposals reviewed
 - ✓ All reviews that accompany the proposals
 - ✓ Copies of approved consent documents, including forms, adverts etc.
 - ✓ All progress reports submitted by researcher(s), institution(s) and sponsor(s)
 - ✓ All reports of injuries to participants and adverse events.
 - ✓ Attendance at meetings.
 - ✓ Date proposals submitted and date approval given. Financial records.

HREC Records & Reports

- Minutes of HREC meetings which shall be in sufficient detail to show:
 - ✓ Attendance at the meetings.
 - ✓ Actions taken by the HREC.
 - ✓ The vote on these actions including the number of members voting for, against, and abstaining.
 - ✓ The basis for requiring changes in or disapproving research.
 - ✓ A written summary of the discussion of controversial issues and their resolution.

HREC Records & Reports

- Records of continuing oversight activities.
- Copies of all correspondence between the HREC and applicants, researchers, sponsors, and any other agent consulted by HREC in the discharge of its duties.
- Statements of complaints or information/data used to determine decision(s) on research.

Summary

- Conduct of scientific research in an ethically sound way should be the focus of research ethics committees
- In order to achieve this, both the research ethics committees & investigators have shared responsibilities
- There are regulations that guide the conduct of REC business in reviewing protocols

Conclusion

- Investigators are also expected to comply with regulations guiding the development & submission of research proposals for ethical review
- This paper highlighted these guidelines
- Strict compliance to these regulations will increase the realization of safe ethical studies.