

Relationship of Ethics Committees to other Ethics Committees, Institution, NHREC, other Regulatory Agencies etc.

By

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Introduction

- Running ethics committees require knowledge of the internal & external mechanisms guiding relationships
- These relationships pertain to the connectedness & mutual dealings within ethics committees, and also between ethics committees & investigators

Introduction

- The overall focus of this is to build an efficient system where the roles, expectations and responsibilities of each party are fully understood, carried out and appraised periodically
- These are tools necessary for the enforcement of ethical standards and protection of human participants in research
- This lecture highlights the guidelines contained in Section K of the NCHRE

HREC Records & Reports

- HREC shall prepare and maintain adequate documentation of all its activities including the following:
 - 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
 - All progress reports submitted by researcher(s), institution(s) and sponsor(s).

HREC Records & Reports

- HREC shall prepare and maintain adequate documentation of:
 - All reports of injuries to participants and adverse events.
 - Attendance at meetings.
 - Date proposals submitted and date approval given.

HREC Records & Reports (Minutes of meetings)

- 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 (Minutes of Meetings)

- 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.

HREC Records & Reports (Submission Requirements)

- The applicant applying for ethics review must submit the following:
 - ✓ 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, trade publications, audio, video and web Advertisements
 - ✓ Copy of brief curriculum vitae (2–3 pages) of the
 - ✓ principal investigator(s)

HREC Records & Reports (Submission Requirements)

- ✓ Copy of letter(s) of support from co-investigator(s), laboratories & sources of required resources.
- ✓ Where applicable, letter of sponsorship.
- ✓ One page plain language summary of the research.
- ✓ 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.

HREC Records & Reports (Submission Requirements)

- ✓ 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.

HREC Records & Reports

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

HREC Records & Reports

- This report shall contain brief summary statistics about the research:
 - ✓ no of participants recruited & their breakdown
 - ✓ no of adverse events, complaints and their resolution,
 - ✓ any ongoing investigation or review & copies of any publications, including-reports or abstracts arising from the research.

HREC Records & Reports

- 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.

HREC Records & Reports

- 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

Conclusion

- Conducting researches with the inclusion human participants require precision and scientific rigor
- This begins with the quality of protocol development, review process, and monitoring of research
- Achieving this is a joint responsibility of investigators and ethics committee members

Conclusion

- The records to be kept and processes adopted in assuring quality in the functioning of ethics committee and relationship with research teams was the focus of this lecture
- Adherence to these standards would facilitate the realisation of scientifically and ethical valid researches