Ethical Review Processes III (Annual Reports & Continuing Review)

Temidayo O Ogundiran
MBBS (Ibadan), MHSc (Toronto), FACS, FRCS (Edinburgh), FWACS

Division of Oncology, Department of Surgery, University of Ibadan and University College Hospital, Ibadan
West African Bioethics Programme, University of Ibadan, Nigeria

Annual Reports

- Progress reports about on-going research are to be submitted by researchers (+ institution and sponsors) to the HREC
- Should be submitted to HREC when applying for annual renewal of research protocol

Annual Reports

- conduct of research
- number of patients recruited, that dropped out or lost to follow up
- adverse events
- challenges, logistics problems, etc.

Continuing Review

- Revisions to an approved study
- Protocol renewal
- HREC review of adverse events
- Data and safety monitoring
- Sundry Issues
- Closure of study

Revisions to an Approved Study

All study amendments, modifications, revisions, addenda, updates, administrative changes, additions, & other study changes must be reviewed and approved by the HREC prior to initiation

Minor Revisions

- Involve procedures that are no more than minimal risks
  - Examples: change in telephone nos, addition or deletion of staff, reduction in number of research participants, deletion of questions in a survey, etc.
- An expedited review process may be used

Substantive Revisions

- Any revision that involves increased risk to subjects or significantly affects the nature of the study
  - Examples: revision to recruitment plan, revising eligibility criteria, adding a research site, changing the consent form, adding a PI, etc.
- Requires a full HREC review

Protocol Renewal

- Renewal of on-going research protocols at intervals no less than annually
- A monitoring mechanism for continuing safeguards and welfare of study participants

Protocol Renewal

- Some issues to note at renewal:
  - accrual, revisions, unanticipated toxicity, subjects complaints, new risk/benefit information, etc.
- May undergo full HREC or expedited review

HREC Review of Adverse Events

- Occurrence of adverse events may change the risk/benefit calculus of an on-going research depending on severity
- A valid review may impact on continuation of research, revision of consent document, re-consenting of enrolled participants, etc.

Data & Safety Monitoring

- Ongoing data and safety monitoring throughout the life of the study
- Options for monitoring:
  - Individual Investigator, Study Sponsor's Data Monitoring Committee, Data and Safety Monitoring Board (DSMB)
- HREC to determine which, and review data and safety issues

Data & Safety Monitoring Board

- A multidisciplinary group of 3 to 6 people with expertise in medical issues, clinical trial method(design, data management, statistics), +/- research/biomedical ethics
- No professional or financial interest in study

Data & Safety Monitoring Board

- Needed in studies with: large study population, multiple study sites, highly toxic therapies or dangerous procedures, high expected rate of morbidity/mortality, high chance of early termination

Data & Safety Monitoring Board

- Review data at predetermined intervals during the study
- Communicate findings to all HRECs involved in multiple site studies
- May recommend modification or stoppage of study based on the following reasons: **efficacy**, **futility** and **safety**

Sundry Issues

- HREC should address reports of noncompliance, complaints, deviations, or an eligibility exception notice

Sundry Issues

- Such reports may emanate from: participants or their family members, a whistle-blower, a member of the research team, HREC internal audit system, etc.

Sundry Issues

- HREC should have a written policy to address such promptly, professionally and fairly

Closure of Study

- Investigators are required to submit final reports to HREC after completion of studies
- There is no clear cut definition of when a study closes

Closure of Study

- IRBs practices of study closure: administrative, board review, e-mail notification, PI filling out a form, etc.
- HREC should develop a formal procedure for study closure

Resources & Further Readings

- National Code of Health Research Ethics, Federal Ministry of Health, Abuja, Nigeria, 2007
- Institutional Review Board: Management and aFunction by Elizabeth A. Bankertand Robert J. Amdur Chapter 7
- Institutional Review Board: Management and Function by Elizabeth A. Bankertand Robert J. Amdur Chapter 5