Composition Functions and Management of Ethics Committee

Clement Adebamowo
What is research

• Research as defined has 2 components:
  – *Systematic investigation*, including research development, testing and evaluation
  – Designed to develop or contribute to *generalizable knowledge*.

• Research is further classified as
  – Therapeutic procedures – interventions administered with the intent of providing direct benefit to the research participant
  – Non-therapeutic procedures – interventions that are not administered with therapeutic intent and are only intended to answer the scientific question of the study
Exemption from review

• HREC may grant exemption from review where
  – Research is conducted in established or commonly accepted educational settings involving normal educational practices such as
    • Research on regular and special education instructional strategies
    • Research on the effectiveness of or comparison among instructional techniques, curricula or classroom management methods
  – Research involving the use of educational tests (cognitive, diagnostic, aptitude and achievement), survey procedures, interview procedures, or observation of public behavior unless:
    • Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to participants
Exemption

- Where any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability or reputation

  - Research involving collection or study of existing data, documents, records, pathology specimens, or diagnostic specimens if these sources are publicly available (note that this refers to the availability of the data and not to the status of the custodian of the data) or if the information is recorded in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to the participants
Exemption

- Studies that are meant to evaluate the outcome of procedures, programs and services are exempt because they are designed to produce information leading to improvement in delivery of procedures, programs and services. Such studies usually evaluate measures that are already in use and considered part of standard practice. They may include the collection and analysis of data or collection of new data but they do not involve allocation into groups or randomization.

- Studies that are designed to evaluate or assess quality of services, programs and procedures and formulate guidelines leading to their improvement are exempt. Such studies may also involve collection and analysis of data.
Exemption

• Innovative or non-validated medical treatment – treatment that is designed solely for the benefit of the patient but in which the ability of the treatment to result in the desired result is to some degree not proven. Such activities are exempt while recommending that they should be subjected to research in order to generate information about their efficacy as soon as possible.

• Clinical audit – where the study is designed and conducted solely to define or judge only current care, without reference to a standard. It may involve collection and analysis of data but there is no allocation to intervention groups or randomization and the services have been delivered before the audit is initiated.
Exemption

• All exemptions are determined by the ethics committee

• Applicants seeking exemption shall submit the proposed research (where it is research) or a write up containing adequate information (sufficient in the judgment of the HREC to be able to make a determination) about the work to the HREC

• Exemptions may be granted by the HREC chairperson or his designee from among members of the HREC in consultation with the HREC administrative officer

• In granting exemption, the reviewer shall exercise all the powers of HREC except that they may not disallow the research/activity

• The Chairman shall bring all exempted research to the notice of HREC for notice, discussion and ratification
Process for expedited review

- Research is found to involve no more than minimal risk - meaning that the probability and magnitude of harm is no greater than that encountered in the daily lives of all (or the great majority) persons in the population (under normal circumstances) from which research participants are to be recruited. Note that minimal risk is applicable in non-therapeutic research only.
  - Research represents minor changes in previously approved research during the period for which approval was previously given.
  - Research does not involve vulnerable populations such as children, prisoners, pregnant women etc.
  - Research does not contain serious methodological or ethical flaws.
Process for expedited review

- Expedited review may be carried out by the HREC chairperson or his designee from among members of HREC.
- In reviewing the research, the reviewer shall exercise all the authorities of HREC except that the reviewer may not disapprove the research.
- The Chairman shall bring all research reviewed expeditiously to the next HREC meeting for notice discussion and ratification.
Process for regular review

• Except when an expedited review is done, research proposals shall be reviewed at the regularly convened meetings of the committee at which majority of the membership of the committee are present, including at least one member whose primary concern is in the non-scientific area
• Members can participate electronically
• Process for regular review
  – HREC shall review all prescribed application materials
  – Decisions in HREC shall be arrived at by discussion and consensus or by the votes of a simple majority
  – HREC may, at its own discretion, invite applicant, sponsor, institutional representative or any other individual that is considered pertinent to the review process
Process for regular review

• HREC shall notify investigators in writing of its decision to approve, disapprove or require modification of research.

• HREC shall have a maximum of 3 months from the data of receipt of a valid application to give its decision to the applicant.

• An application is considered valid only after the HREC acknowledges receipt of all materials prescribed by HREC to give a determination.

• Where HREC considers an application of such complexity that it cannot give a determination, the application shall be referred to the NHREC and the applicant duly informed within the stipulated 3 months.
Process for regular review

- Where HREC does not conclude its review within 3 months and has not referred the case to the NHREC, the applicant shall have the right to complain to NHREC with possibility of reallocation of the proposal to another HREC and sanction of the concerned HREC.

- Where HREC decides to disapprove a health research activity, it shall include in its written notification, a statement of the reasons for its decision and give an applicant the opportunity to respond in person or in writing within 3 months of receipt of the notification.
Process for regular review

- Where HREC has received representation from the applicant in response to an existing decision, HREC may decide to uphold or modify its previous decision and shall communicate this decision to the applicant within 3 months of the representation.

- HREC is mandated to keep all its records for a minimum of 10 years after completion of the research activity.
Process for continuing oversight

- HREC shall have continuing oversight of research at intervals adjudged by HREC as being appropriate to degree of risk involved in participation in the research.
- HREC has the authority to examine all aspects and documents including consent forms, questionnaires, case report forms etc. related to the research and necessary for HREC to conduct its oversight function.
- This shall occur at least once a year or once during the lifetime of the study where the duration of the study is less than 1 year, whichever is shorter.
- HREC has the authority to observe or cause to be observed on its behalf, the research and its consent process to ensure compliance.
Process for continuing oversight

• HREC may initiate the process of oversight of research in the event of receipt of complaints, information or data relevant to the research from any source.
Amendment of protocol

- Where there are changes in the sponsorship, institutional guidelines, institutional structure, HREC requirements, national laws or exigencies that impact on the ethical conduct of research

- However HREC shall require the researcher to submit an application for original research approval where in its opinion, the proposed amendments are substantial, such as but not limited to changes in inclusion or exclusion criteria, randomization, interventions and outcome measures

- Under no circumstances shall a research deviate from approved protocol except as is necessary to eliminate immediate hazard to research participants
Amendment of protocol

- In this case, the researcher shall inform the Chairman of the HREC within 24 hours of such changes.
- In such circumstances as described above, the researcher shall stop the research and the HREC shall conduct a thorough review of the research before authorizing suspension, continuation or modifications to the research.
Suspension of research

• HREC has authority to suspend research when the research is not being conducted
  – In accordance with HREC requirements
  – In accordance with existing legislation
  – In accordance with institutional guidelines
  – Where there is unexpected serious harm to participants

• Any suspension shall include a statement of the reasons for the HREC’s action and shall be reported within 2 weeks to the researchers, institutions, sponsors and NHREC

• Any of these individuals are entitled to ask for a reconsideration of the decision of HREC within 2 weeks of receipt of notice of suspension
Revision of suspension

• HREC may revise its decision to suspend if the precipitant of HREC’s action is satisfactorily resolved.

• In all cases of suspension, the revision shall occur at the next regular meeting of HREC.

• HREC may require the researcher to sign an agreement with HREC on its findings and agreed remedial measures.

• Where HREC allows resumption of research, an oversight review of the research must be carried out within 6 months or at least once during the lifetime of the research if it is shorter than 6 months.
Termination of research

- Where the researcher, sponsor or institution is unable to offer or the HREC is unable to ascertain or enforce satisfactory remediation of the precipitant of the suspension, the HREC shall terminate the research
- HREC shall indicate the reason for its termination in writing
Protocol renewal

- Ethics committee approvals are given for one year only
- This gives the ethics committee opportunity to do a continual review of the research and ensure continued safeguard of research participants
- Ethics committees should send reminders to researchers about their protocol
- Ethics committees require different ranges of materials for the review process. As a minimum, information about number of participants recruited, any adverse event, complaints and new information that may affect the risk/benefit analysis of the study
Reporting of adverse events

- Occurrence of adverse events (AE) may reflect a change in the risk/benefit of research
- Ethics committee must therefore evaluate all AE
- The objective is
  - To ascertain whether the study should continue
  - To ascertain whether enrolled participants should be re-consented
- In multicenter studies, AE occurring at any site should be reported to all ethics committees of record
- In clinical trials, all AE must also be reported to the drug regulatory agency (NAFDAC)
Reporting adverse events

- An AE report should contain
  - Description of the AV in detail that allows an informed review of the occurrence
  - Explanation of why the event was unexpected, related to study and serious
  - Describe changes to the research protocol, the consent form and a need to re-consent in order to minimize further risk of the event
  - If no changes are proposed, the rationale for continuing the study in the same way should be provided
  - Update the risk analysis of the study
Limits of Ethics Committee authority

- The Ethics Committee is not an editorial service. The Committee reviews the consent document whether it clearly and accurately describes the essential elements of informed consent in language appropriate for the study population.
- If the Committee decides that this criteria is not satisfied, the study cannot be approved.
- Where a researcher is not motivated enough or does not recognize the basic goal of the consent document, then he should not be doing research.
Limits of Ethics Committee authority

- The Ethics Committee is not the office of the Hospital Medical Director
- The Ethics Committee does not make policy for non-research activities in medical centers for example on where the Committee discovers that the care provided is lower than standard of care, it may recommend to the institution that this needs to be revised
Limits of Ethics Committee authority

- Ethics Committees need to recognize that many projects that involve a systematic evaluation of medical records and that these are not research. Examples include Quality assessment, education, outcome, etc.
- Ethics committees need to know that linkage of medical and research records risks breach of confidentiality. However when medical records are being reviewed for purposes other than research, the ethics committee has no jurisdiction over that.
Limits of Ethics Committee authority

- Ethics committees are not that part of the institution that advises the leadership on ways to avoid or minimize problems that could lead to charges of criminal activity, civil misconduct, or regulatory non-compliance. This is a role for the institutions’ legal team, though a member of this legal team may be on the ethics committee.

- Ethics committees may identify liability issues in an establishment and inform management but cannot mandate reforms before study/protocol approval.
Limits of ethics committee authority

- Ethics committees are not Data Safety Monitoring Boards (DSMB)
- During review of research, ethics committees are supposed to determine whether there is an appropriate system in place for monitoring the study with respect to unexpected reports of inefficacy or toxicity