Ethics Committee Training & Disciplinary Powers

By

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Introduction

- In order to assure of human capacity development, and standardisation of training, the NCHRE spells out the nature and quality of research ethics training required of research ethics committee members
- This is required to equip research ethics committee members with skills adequate to contribute meaningfully to the process of ethical reviews

Introduction

- In order to ensure discipline and diligence in ethical review process, the establishment of many support service bodies are necessary
- This lecture highlights the training requirements of ethics committee members, as well as the roles and responsibilities of support such bodies as contained in the NCHRE

HREC Education & Training Responsibility

- HREC shall organise, cause to be organized on its behalf, sponsor, support or associate with training and educational programs for biomedical, social and behavioural sciences' researchers.

HREC Education & Training Responsibility

- In order for such programs to be accepted for purposes of membership of HREC and as evidence of satisfactory training of biomedical researchers for purposes of research review, the curriculum must be certified by NHREC.

HREC Education & Training Responsibility

- Suitable educational programs must contain modules on national code of health research ethics, principles of research ethics, functions of HREC, research integrity and misconduct.
- Additional training in research methodology and administration may also be provided

Independent Educational & Training Activities in Research Ethics

- Suitably qualified individuals and organizations shall have the right to provide training programs in research ethics for biomedical, social and behavioural sciences' researchers.

Independent Educational & Training Activities in Research Ethics

- For such programs to be acceptable for the purposes of membership of HREC and considered adequate training of biomedical researchers applying for review of research, the curriculum must be certified by the NHREC.

Independent Educational & Training Activities in Research Ethics

- Suitable educational programs must contain modules on national code of health research ethics, principles of research ethics, functions of HREC, research integrity & misconduct.
- Additional training in research methodology and administration may also be provided

HREC Research Ethics Consultation & Clinics

- HREC may conduct ethics' clinics and consultations, at its own discretion, and upon payment of fees, as it may determine, for the purposes of providing advice to researchers during the development of research protocols or during the conduct of research.

HREC Research Ethics Consultation & Clinics

- Such clinics and consultations shall be rigidly separated from the process of ethical review of research and shall not have any effect on HREC review or oversight functions

Relationship With Other Regulatory Agencies & Oversight Bodies

- The FGN acting through any of its organs and establishments has the overall duty of protecting the welfare of the citizens of Nigeria.

- It may therefore exercise all the powers of protecting citizens according to the law, including citizens participating in research.

- In addition, some agencies of state in discharge of their duties according to law may also exercise regulatory functions within the research environment.

Oversight of Clinical Trials by NAFDAC

- NAFDAC (agency responsible for registration of new finished products for sale or use as food or drugs in Nigeria).
- It therefore exercises regulatory functions in the conduct of clinical trials to test efficacy and safety of such products.

Oversight of Clinical Trials by NAFDAC

- NHREC is responsible for ensuring that all research including clinical trials are conducted according to the highest ethical and scientific standard.

Oversight of Clinical Trials by NAFDAC

- Clinical trials involving new finished products in Nigeria therefore require the permission of NAFDAC and compliance with both the clinical trials guidelines issued by NAFDAC and the National Code for Health Research Ethics.

Oversight by Institutions

- Institutions where research is conducted may elaborate guidelines for the conduct of research in accordance with their enabling law and consistent with the need for maintenance of the highest ethical and scientific standard as outlined in this code.

Oversight by Institutions

- Oversight by other committees such as:
  - data safety monitoring boards,
  - biosafety committees,
  - scientific committees,
  - community advisory committees etc.

Oversight by Community Advisory Committees (CAC)

- CAC are established by the study investigators depending on the nature of the proposed research, the research site, the study base or on the recommendation of either the institution research is based or the HREC supervising the research.

Oversight by Community Advisory Committees (CAC)

- They are important forums for facilitating dialogue between community members, research participants and researchers. CAC members should be identified from communities where research is to be undertaken through a stakeholder consultative process.

Membership of the CAC

- ✓ Persons with understanding of local laws, cultural values & gender issues
- ✓ Peer leaders
- ✓ Religious leaders
- ✓ Representative of the study population
- ✓ Professionals who understand research or science issue
- ✓ Community leaders
- ✓ Representatives of the research team who should form no more than 20%

Roles & Responsibilities of the CAC

- Primary to assist investigators understand and incorporate community concerns into their research activities e.g. advising on; issues central to the informed consent process, participants' recruitment and retention, etc.

Roles & Responsibilities of the CAC

- Responsibilities vary according to the study location, size, etc, but generally, they are to:

  I. provide information on traditional beliefs and needs of the study population and their concerns regarding research

  II. provide advice and support regarding recruitment and retention of participants in the research including gender equity

The Institutional Biosafety Committees (IBC)

- IBCs are established by institutions that undertake research on classified hazardous substances of physical or biological nature.
- Each IBC formed shall consist of a biosafety officer and at least three other officers with appropriate expertise.

The Institutional Biosafety Committees (IBC)

- The IBC shall comply with regulations and guidelines contained in the sub-code regarding research on hazardous substances issued by the NHREC.
- The IBC shall be registered with the NHREC.
- It is the responsibility of researchers to notify and provide to the IBC, the research proposal involving classified hazardous substances of physical or biological nature.

The Institutional Biosafety Committees

- The IBC shall minimize potential human and environmental risks associated with research on or with classified hazardous substances such as pathogens, radioactive material and applications of biotechnology especially recombinant DNA techniques and processes.

The Institutional Biosafety Committees

The IBC shall:

- Notify the NHREC of any research with hazardous substances in their Institutions
- Conduct biosafety review of research proposals on hazardous substances
- Institute a health-monitoring programme for all highrisk personnel involved in application, use and production of restricted categories of classified substances.

The Data & Safety Monitoring Boards

- Is an independent group of experts established by the study sponsors to review safety data during a clinical trial.
- Ensures that the study is conducted and the data are handled in accordance with the provisions of the protocol and monitors adverse events and safety data.

The Data & Safety Monitoring Boards

- As appropriate, DSMB should be established before the commencement of the clinical trial and its membership submitted to the HREC for their record.
- All interventional studies including drug efficacy trials, & all clinical trials should have a safety monitoring plan which will be implemented through the DSMB.

Membership of the DSMB

- Individuals with appropriately training and scientific knowledge in all aspects of research
- At least three individuals including a clinician with competence in the research field of the trial and a statistician
- Individuals who are independent of the clinical trial and the sponsor.

Membership of the DSMB

- People with adequate medical, pharmaceutical, scientific, biostatistical and/or ethics qualifications and clinical trial experience. The qualifications most appropriate for a specific DSMB will depend on the nature of the clinical trial and of the product under investigation

The Functions & Responsibilities of DSMB

I. Ensure safety of study participants

II. Preserve the integrity and credibility of the trial

III. Ensure availability of definitive and reliable results in a timely manner

IV. Make decisions related to the safety of the study, based on the submitted results and adverse event reports on whether the study should continue or not

Things the DSMB must Report to the Sponsor(s) of the Trial, HREC & Institutional Officials

- Concerns over differences in serious adverse events between study arms
- Serious social harms
- Concerns about the conduct of the trial
- Concerns about data integrity
- Whether the study should be terminated or continued based on safety and interim data

DSMB Considerations Prior a Study

- Mode and time frame for receiving adverse events reports
- Frequency of receiving data
- Frequency of meetings to review the data and adverse event reports at hand. (Where there may be any element of concern, the DSMB may chose to review the data more frequently
- Channels of communication with the Principal Investigator, IRC and sponsor where necessary on decisions reached by the DSMB

Conclusion

- Chances exist that without these regulations, ethics committee members could pay less attention to quality and sound training
- This could affect the composition and quality of ethical reviews

Conclusion

- The need for the establishment, roles, and responsibilities of related support bodies were also highlighted in this lecture
- If all ethics committees, and relevant stakeholders adhere to these standards, the chances of assuring quality in the process and outcome of ethics committee would be higher