

# **Introduction to Nigerian National Health Research Ethics Committee and the National Code for Health Research Ethics**



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# Nigeria's baby steps



- National Health Research Ethics Committee has the following membership
  - Chairman appointed by Hon. Minister of Health
  - Membership representing Law, Pharmacy, Medicine, Nursing, Community Health Workers, Christians, Muslim, Researchers and 3 other persons
  - Ex-officio members from Ministries of Education, Environment, Women's affairs, Agriculture etc. NAFDAC, NUC

# Functions of NHREC



- Determine guidelines for the functioning of health research ethics committees
- Register and audit health research ethics committees
- Set norms and standards for conducting research on humans and *animals*, including norms and standards for conducting *clinical trials*
- *Adjudicate* in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by a health research ethics committee

# Functions of NHREC




- Refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider
- Institute such *disciplinary action* as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act
- Advise the Federal Ministry of Health and State Ministries on any ethical issues concerning research

# Functions of HREC



- Review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
- Grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.

# National Code for Health Research Ethics

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- Philosophical approach taken
    - Concise
    - General guidelines only
    - Includes both philosophical principles and operational methodology
    - Flexible
    - Comprehensive

# Highlights of the code



- Definition of research as systematic investigation designed to generate generalizable knowledge
- Identification of activities exempted from research and allocation of the power of determination to HREC, for example
  - De-identified publicly available data
  - Innovative medical practice
  - Audit and Quality Assurance studies

# Highlights



- Registration of HRECs to create a National Database and Categorization of HRECs
  - HRECs being audit programs must have direct lines of communication with heads of proposing institutions
  - HREC members must complete NHREC approved training programs in research ethics
  - Institutions must provide HRECs with space, office, staff and infrastructure to enable them do their work
  - Institutions shall provide coverage of HREC members from liability



# Highlights



- HRECs shall apply for initial registration and re-registration every 2 years
  - Submission of materials required, including copies of financial statement, evidence that previous commitments by the institution are met and evidence of continuing training of HREC members
  - Limitation of HREC's authority to the bounds of proposing authority
  - Institutions that have no HREC can set up collaborative agreements with registered HRECs
- HREC membership must always include a lawyer
- Institutions can have more than 1 HREC

# Highlights



- Provision of liability coverage for members of HRECs
- HRECs shall include at least 1 lay person
- HREC members are bound by a perpetual code of confidentiality
- HRECs shall have continuing oversight of research – a review shall be conducted at least once a year or during the life of the study whichever is shorter
- NHREC shall categorize HRECs and define limits of activities
- Clear processes for expedited review, exception and amendment

# Highlights



- HRECs can co-opt members
- Encourages researchers to be invited to HREC meetings
- Sets time limits for decision on research applications – 90 days
- All records relating decision must be kept for at least 10 years
- Clear process for suspension, revision of suspension and termination of research
- Clear adjudicatory mechanism to NHREC

# Highlights



- Review of multi-institutional research
  - Procedure of 3 or fewer and more than 3 collaborating sites
  - Options for research review
  - Opportunity for central research review
  - Requirement for sharing ethics review from different ethics committees
  - Requirement for Materials Transfer Agreements, Benefits sharing, IPP, patent and other tangible and intangible benefits' sharing

# Highlights



- Only applicant(s) with qualification(s) and background sufficient to serve as principal investigator(s) and based in an institution in Nigeria that is capable of carrying out the research shall apply for review of research
- HREC may adopt the result of review by another HREC rather than conduct a fresh review
- NHREC may review research
  - Nationwide research or more than 3 sites
  - Research referred to NHREC from HREC
  - There is no HREC in an institution and no collaborative agreement with an institution that has one

# Highlights



- NHREC review of research
  - Mandating review by a HREC anywhere in the country as the HREC of record
  - Constituting an *ad hoc* HREC
  - Constituting itself into a HREC
    - Oversight will still be provided by local HRECs
- Incorporation of ethics guidelines in code for guidance during research review
- Ethics guidelines goes beyond the “4” principles to accommodate recent advances in ethics and emphasizing the role of community, trust, truth telling, GCP and GLP

# Highlights



- HREC may charge fees
- Informed consent documents must be legible and not more than 8 pages long
- All consent activity must be documented
- HREC must organize training for members and the community of the proposing authority
- HRECs may offer consultation services to researchers
- HRECs will demand that researchers submit evidence of recent training in research ethics
- NHREC will exercise oversight functions on HRECs

# Highlights



- HRECs have disciplinary and compliance powers
  - Include suspension of research
  - Termination of research
  - Recommendation to NHREC for disciplinary action
- NHREC disciplinary powers
  - Debarment of researchers
  - Imposition of disciplinary measures
  - Report to police
  - Report to other ethics regulatory agencies in case of international collaborative research



# Current activities



- Code has been released and can be found at <http://nhrec.net> where you have the opportunity to either read or download it
- Comments can be sent to [secretary@nhrec.net](mailto:secretary@nhrec.net), [deskofficer@nhrec.net](mailto:deskofficer@nhrec.net) or [chairman@nhrec.net](mailto:chairman@nhrec.net)
- Sub-codes for children, pregnant women, prisoners, people living with AIDS, and others are in development
- Standard Operating Procedures (SOPs), prototype MTA, consent forms etc are available on NHREC website

# NHREC website



Promoting Highest Ethical and Scientific Standards  
for Health Research in Nigeria

Welcome to  
National Health Research  
Ethics Committee, Nigeria

SEARCH

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## National Health Research Ethics Committee, Nigeria



Promoting Highest Ethical and Scientific Standards for Health Research in Nigeria



### News:: National Health Research Ethics Committee, Nigeria

The Honourable Minister of Health of the Federal Republic of Nigeria inaugurates the National Health Research Ethics Committee of Nigeria. In His speech; He said this government will continue Her efforts to reposition the health sector into one that is responsive to the needs of the citizens, and shall embarked on a fundamental and far reaching health sector reform



### NHREC Draft Code

The Draft of National  
Code for Health Research  
Ethics [Now Available](#)



### Mission and Function of NHREC

Grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.....



### Contact Us Today

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### NHREC CODE

Nigerian Code of Health  
Research Ethics