

Introduction to National Code for Health Research Ethics of Nigeria

by

Adebayo O. Adejumo

RN. PhD. FWACN

Member, National Health Research Ethics Committee of Nigeria (NHREC)

Faculty Member, West African Centre for Bioethics

bisiandbayo@yahoo.com (234-803-491-9002)

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**The Institute of Human Virology
Abuja, Nigeria**

April 28, 2011

Introduction

There were earlier attempts in the 1980s to establish a research regulatory agency in Nigeria

It was however not very active because of

- Limited interest and commitment
- Low level of support and funding
- Low levels of research activities
- Relatively low level of expertise

Introduction

- Research activities continued without adequate regulation
- This might have led to various scientific and ethical lapses in research in the country
- The 1996 Pfizer's Trovan clinical is a typical case study with alleged ethical abuse of vulnerable research participants-An out of court settlement is one of the issues in current research ethics controversy

Need for Research Ethics Regulation

Was informed by:

- History of research abuses in local and international research environments
- Health reforms in Nigeria especially during President Obasanjo's regime
- Need to protect research participants

History of the NCHR

- The FMOH in Nig. was prompted by the need for a national guideline for regulating health (local and collaborative) research in Nigeria.
- In 2006, the FMOH consulted the Center for West African Bioethics in Ibadan, Nigeria
- To develop a broad based document to address peculiar research ethics challenges in Nigeria within the context of our society and local and international research ethics guidelines.
- The NCHRE was established during the tenure of Prof. Eyitayo Lambo as the Minister for Health

WABTP Tech Comm. Members



Uniqueness of The Nigeria National Code for Health Research (NCHR)

- Offers a more practical and culturally adaptive ethical guideline to research in Nigeria.
- Section F of the Code contains a detailed analysis of what clinical investigators should consider when conducting human researches.
- The guidelines are readily applicable in social sciences' research

The Nigeria National Code for Health Research (NCHR)

This document stresses that ethical researches must:

- (a) have social or scientific value to participants/population
- (b) have scientific validity: clear scientific objective(s), valid methodology etc.
- (c) ensure fair selection of participants
- (d) make valid attempts to minimize risks and maximize health related benefits.
- (f) fulfill the guidelines for informed consent process
- (g) guarantee respect for potential and enrolled participants.
- (h) guarantee the trust relationship between investigator and potential participants
- (j) conducted in accordance with the principles of good clinical and laboratory practices

Membership of the NHREC

The NHREC was set up in 2006 . Members include a Chairman and members representing:

- Law
- Pharmacy
- Medicine
- Nursing
- Community Health Workers
- Christians
- Muslims
- Researchers
- and *ex-officio* members from Ministries of Education, Environment, Women's affairs, Agriculture etc. the national drug regulatory agency (NAFDAC), the national universities commission (NUC)

NHREC & Fmr Min. of Health



Functions of NHREC in the NCHR

- 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 (2)

- 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
- The NHREC has issued a National Code for Health Research Ethics

The NCHR & Health Research Ethics Committees (HRECs)

- Registration of HRECs to create a National Database and Categorization of HRECs
- HRECs 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 of the Nigerian Code

- HREC shall apply for initial registration and re-registration every 2 years
- The authority of an institutional HREC is limited to the boundaries of the establishing authority to prevent shopping around for the most lenient Ethics Committee
- Institutions that have no HREC can set up collaborative agreements with registered HREC
- HREC membership must include a lawyer whenever feasible

Highlights of the Nigerian Code

- EC members are bound by a perpetual code of confidentiality
- EC must conduct oversight of research at least once a year or during the life of the study
- The code includes clear processes for full review, exception, full committee review and amendment
- Sets time limits for decision on research applications
– 90 days
- Clear adjudicatory mechanism to NHREC

Highlights of the Nigerian Code

- 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, patent and other tangible and intangible benefits' sharing

Highlights of the Nigerian Code

- NHREC may review research
 - Nationwide research or where research will take place in more than 3 sites
 - Research referred to NHREC from any HREC
 - Where an institution has no EC and no collaborative agreement with an institution that has one, whereas researchers want to conduct research in the institution or in its catchment areas

Highlights of the Nigerian Code

- NHREC review of research could also be done by
 - 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
- 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 of the Nigerian Code

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

Highlights of the Nigerian Code

- 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

Opportunities

- Nigeria like most developing countries has a unique opportunity to put in place a comprehensive framework for the protection of health research participants
- Such framework will take advantage of the history of research ethics in other countries, best practices, international guidelines and recommendations, and best evidence from research ethics literature
- It can also avoid some of the mistakes of the more established countries on issues like multiplicity of guidelines or different authorities issuing guidelines for different aspects of research in same country, elaborate bureaucracy and paperwork, legalisms etc

Challenges

- Funding of ethical regulatory infrastructure in an environment of multiple competing needs has been a major challenge
- Traditionally lax compliance with laws and regulations in other spheres of national life affects attitude to ethical regulations
- Limited opportunities for training
- Limited resources

Challenges

- Because the National Guidelines was predated by many institutional committees whose work was based on EU, US, or WHO guidelines, accession to and compliance with National Guidelines has been fairly slow
- While administrative support was easy, getting legislative support in a nascent democracy has proved challenging
- The National Health Bill under which the NCHRE & NHREC has gone beyond public debate & committee deliberations, it is awaiting final passage by the National Assembly

Current activities

- Code has been released and can be found at <http://www.nhrec.net> where you have the opportunity to either read or download it
- Comments can be sent to secretary@nhrec.net, deskofficer@nhrec.net or 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

National Health Research Ethics Committee, Nigeria

Promoting Highest Ethical and Scientific Standards for Health Research in Nigeria

Welcome to
National Health Research Ethics Committee, Nigeria

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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
Federal Secretariat Complex Shehu Shagari Way, Garki, Abuja P.M.B. 083, Garki-Abuja

NHREC CODE

Nigerian Code of Health Research Ethics

Acknowledgment

- Professor Adebamowo's ideas and opinions shared at the UNESCO meeting in Nairobi formed the foundation on which these slides were predicated
- Members of staff of the Nigerian National Health Research Ethics Committees
 - <http://nhrec.net>
- Members of faculty and administrative staff of West African Bioethics Training Program
 - <http://www.westafricanbioethics.net>

Thanks for listening!

