Overview of the Human Research Participant Protection System in Nigeria

being the topic of a presentation by

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Background

- Efforts by Nigerian authorities to institutionalize health research dates back to the early 70's
- Was through the establishment of the Medical Research Council.
- Subsequently efforts to strengthen a national health research system in line with the concept of Essential National Health Research (ENHR) were made but albeit un-successfully.
- This may have been as a result of poor political support, and lack of regulations to promote health research in Nigeria at the time

Background (2)

- Increases in research investments in the last 2 decades from the WHO/TDR, EDCTP, etc helped to reawaken the interest of the Govt in health research.

- 2006 turned around health research in Nigeria

- Many initiatives to strengthen health research took place

Include:

i. Technical Panel Meeting on Essential National Health Research (ENHR) in Feb.

ii. High Level Ministerial Meeting on Health Research for Development held in March & June, 06.

The 2 initiatives were locally initiated by the Nigerian FMoH

FMoH & Research Policies

- The 1988 National Health Policy (Revised in 2004) gives the FMoH mandate to oversee health research
- The Federal Ministries of Education and Science and Development were included; being stakeholders as overseers of universities & research institutes
- The FMoH Dept of Health Planning & Research as secretariat, develop policies, set national priorities and coordinate health research nationwide.
- Occasionally, health research processes are dictated partly by the whims of the researchers, institutions; or donor-driven.

Research Ethics Governance and Regulation

- Research ethics in Nigeria, like in many African countries, is only recently receiving attention
- Most developing countries are only recently developing guidelines.

- In South Africa, although an ethics committee since 1966, but it was after 31 years that the Govt issued a guideline for their operations and functions.

- The oldest ethics committee in Nigeria was established in 1980, but the NCHRE was only issued in 2006, 26 years later.
- IRBs in Nigeria have been established by Nig. Univ. Teach. Hosps & Research Centers based on the US Common Rule

NCHRE: Development Process (1)

- The NHREC developed the NCHRE in 2006.
- WAB led the process, Prof. Adebamowo directed
- The Nigerian Code was developed based on review of current research ethics codes especially the CFR 45 Part 46; CIOMS; Helsinki Declaration; and the ethics guidelines from India, South Africa, etc

- Modified Delphi approach was used.
- Team also considered recent developments in international health research ethics, the Nigerian Constitution and the Federal structure of the country, other relevant laws, the history of research and research ethics in Nigeria.

NCHRE: Development Process (2)

- After 1st first draft, Code was approved by NHREC

- National Workshop of researchers and ethics committee members in University Teaching Hospitals and Research Institutes was conducted in Dec 2006

- This was to discuss the provisions of the Code with potential users and obtain their inputs and ownership.
- Comments, suggestions and corrections received were incorporated by the NHREC
- The improved version was submitted to the government for adoption as the first domestic legal regulation establishing ethical review of research in Nigeria

Legal status

- ECs in Nigeria empowered by guidelines/regulations & Part 4 section 34 of the National Health Act
- In many other countries, there is no legal backing for the existence of ethics committees

- Interest groups, researchers –usually in association with international collaborators –set up ethics committees in order to meet the requirements of funding agencies

- In many institutions, these ethics committees do not last beyond the meeting needed to provide the applicant with ethics approval

NHREC Terms of Reference (1)

(a) set norms and standards for conducting research on humans and animals, including clinical trials

(b) 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 any of the health research ethics committees

(c) register and audit the activities of health research ethics Committees

NHREC Terms of Reference (2)

(d) 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

(e) recommend to the appropriate regulatory body such disciplinary action as may be prescribed or permissible by law against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under the Act

Membership of the NHREC

The National Health Research Ethics Committee 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, NAFDAC, NUC, etc

NHREC MEMBERS

Uniqueness of the Nigerian Code

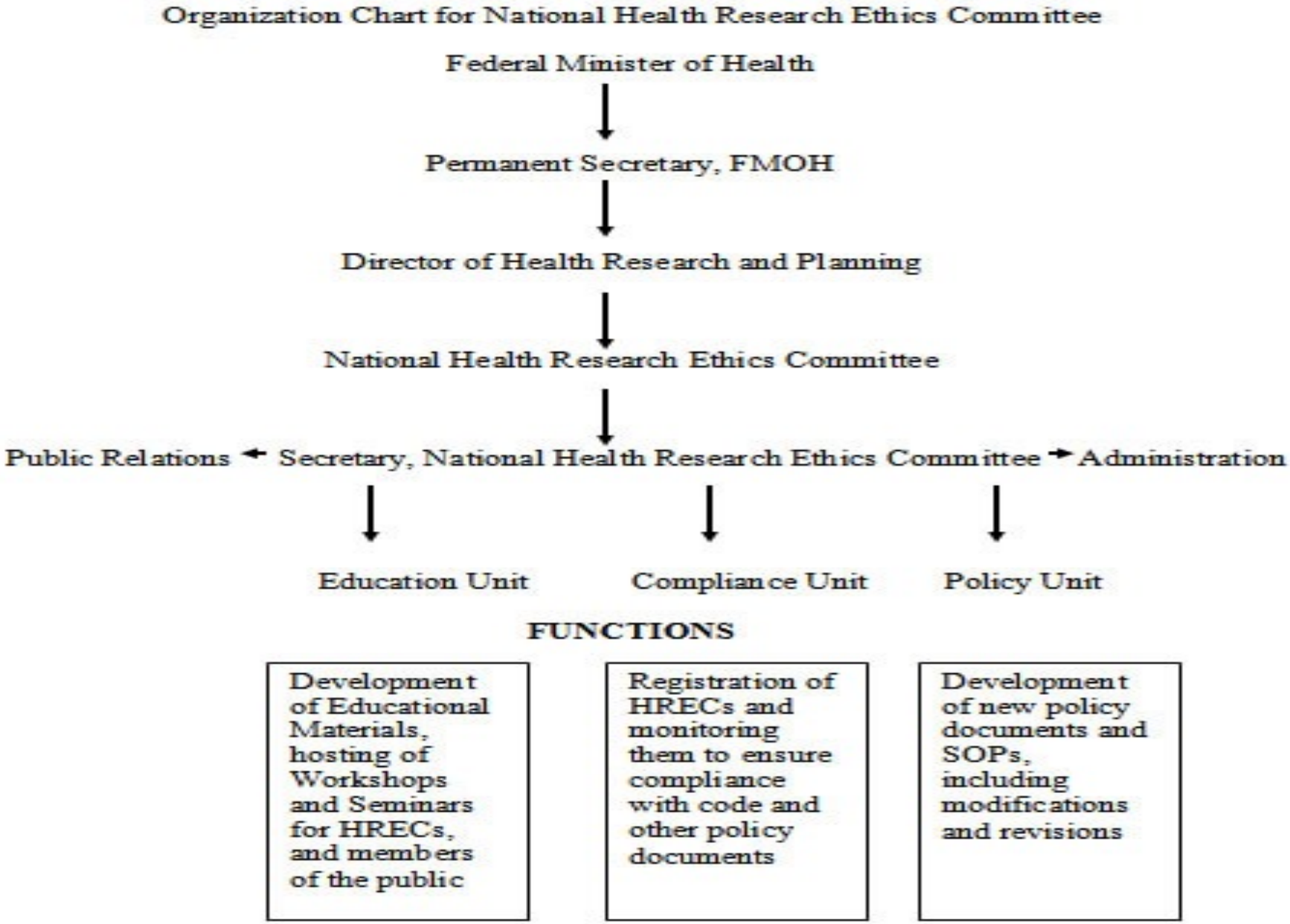
Many ethics regulatory frameworks lack legal authority, but they are rather guidelines adopted by various national and international bodies.

Similarly, the principles on which many of such documents were formulated would hardly ever meet the socio-psychological values across cultures.

As a result, many of ethical codes could not prevent ethical scandals in research.

The document passed through various review and approval processes.

A sub-section of the National Health Act passed into law, and signed by the President


Organization Chart for National Health Research Ethics Committee
Federal Minister of Health
Permanent Secretary, FMOH
Director of Health Research and Planning
National Health Research Ethics Committee
Public Relations
Secretary, National Health Research Ethics Committee
Administration
Education Unit
Compliance Unit
Policy Unit
FUNCTIONS
Development of Educational Materials, hosting of Workshops and Seminars for HRECs, and members of the public
Registration of HRECs and monitoring them to ensure compliance with code and other policy documents
Development of new policy documents and SOPs, including modifications and revisions

Functions of Health Research Ethics Committee (HRECs)

Review research proposals and protocols in order to:

1. 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

2. 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.

Highlights of the Nigerian Code (1)

- Registration of HRECs to create a National Database and Categorization of HRECs
- 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 HRECs members from liability

Highlights of the Nigerian Code (2)

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

Highlights of the Nigerian Code (3)

- 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 (4)

- 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 HREC 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 (5)

- NHREC review of research could be 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 (6)

- 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 HRECs

Highlights of the Nigerian Code (7)

- EC 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

Challenges

- While administrative support was easy, getting legislative support in a nascent democracy has proved challenging

- 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 slow

- While the provision of funding could be used as a method of managing compliance with ethical regulations in developed countries, this tool is not available to many developing countries, many of whose governments do not directly fund research

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
- Some will for no clear reason expect it will soon fail, or it can't work.

Implication for Sierra Leone's research ethics regulation

- Make process all-inclusive and multi-disciplinary
- Basic motivation should be to protect human and animal subjects in research in Sierra-Leone
- Clarify the role of organization in charge of developing new drugs/clinical trials (e.g. FDA/NAFDAC)
- Strengthen the process through parliamentary legislation
- Explore the strengths and weaknesses of similar extant national research ethics regulatory agencies when developing the "Sierra-Leonean model"
- Consider peculiar cultural values of all sections of the people of Sierra-Leone
- Carry all stake-holders along in the entire process
- Focus on global best practices in improving the science and ethics of research

Acknowledgements

A great deal of the information in this presentation were obtained directly from the National Code for Health Research Ethics and also previous publications of Prof. C.A. Adebamowo on the subject

Thanks for listening!