Institutional Structures for Submission and Responsible Conduct of Ethical Research Proposals

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EXCEL RITE CONFERENCE, Abuja, 29th April, 2025

Learning Objectives

- To discuss the requirements/components of ethical conduct of research
- To clarify the institutional structures responsible for ethical conduct of Research
- To delineate the laws and guidelines backing ethics review in Nigeria

Overview

- What is research ethics?
- What are the main requirements for writing and submitting ethical research proposal?
- The National Code for Health Research Ethics
- National Health Act 2014

What is research?

- "Research is a **systematic, deliberate** process of investigation designed to develop or contribute to **generalizable** knowledge (FHI, 2000)"
- Deliberate, intentional, planned effort to investigate & collect information on a given subject
- The goal of conducting research is to contribute to generalizable knowledge
- A gap must exist in knowledge before one can conduct research

The Six Stages of Research

1. Think and **develop a research plan** (proposal)

2. **Submit the plan** to an Ethics Review Committee to get approval

3. Collect **information from field, laboratory (implement the plan)**

4. **Enter information** into the computer, analyse & interpret the data

5. **Write a report** (project, dissertation, thesis)

6. **Disseminate results** (workshop, conference, publication)

Three major phases in research

- Planning for the research (BEFORE)
- Implementation of research (DURING)
- Dissemination of research results(AFTER)
- All these require INTEGRITY

Ethics has important role to play in all stages of research

Considerations for submitting ethical Research protocols

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Requirements for writing and submitting ethical research protocols

1. Research is designed and implemented in ways that generate the knowledge sought (value).
2. There is a planned fair selection of study participants (justice)
3. There is a favorable balance of potential benefits over risks to the participants(beneficence).

Ethical research Requirements -2

4. The study design is methodologically rigorous (application of best practices; comprehensive review of literature, adequate sample with correct method of analysis).

- All scientifically flawed research are unethical to implement (scientific integrity).

5. Planned submission of protocols for Independent review and monitoring of research by a competent ERC

Ethical Research Requirements-3

6. Valid informed consent (understanding and voluntary) planned to be obtained from all study participants (respect for persons).
7. Safety and well being of enrolled participants guaranteed during and after research is completed (respect for persons/beneficence/non-maleficence).
8. Competent persons (investigators and their representatives) will conduct the research.

Ethical Research Requirements-4

9. Findings of study are planned to be disseminated appropriately (feedback to study participants, communities, local and international dissemination).
10. All these conditions are met.

Ethical Research Requirement-Integrity in conduct of Research-5

- Researchers must plan to conduct their science with honesty, responsibility, and professionalism
- This requires that they must;
  - Be well trained
  - Follow the protocol
  - Record all data as observed/heard
  - Never modify or omit data
  - Report honestly, with as little bias as possible
  - Publish findings

Brief History That led to Institutional Structures for Ethics approval-Nuremberg Trials

- When: Following World War II
- Court: International Military Tribunal at Nuremberg.
- Defendants: Leading Nazi doctors
- Charge: War Crimes and Crimes Against Humanity.
- Verdict: guilty of premeditated murder masqueraded as research
- Places: Dachau, Auschwitz, Buchenwald and Sachsenhausen concentration camps.

Nuremberg trial-2

- Characteristics:

  (1) persons were forced to become subjects in very dangerous studies against their will;

  (2) nearly all subjects endured incredible suffering, mutilation, and indescribable pain; and

  (3) the experiments often were deliberately designed to terminate in a fatal outcome for their victims.

  (4) No informed consent of voluntary decision to participate

Nuremberg trial -3

- No ethical consideration before the conduct of the research
- **Experiments designed to gain knowledge on certain wartime conditions**
- The Nazi doctors considered "military necessity" adequate justification for their heinous experiments.
- They justified their acts by saying that the prisoners were condemned to death anyway.

Nuremberg Trial-4

- At the end of World War II, an International Military Tribunal prosecuted Nazi war criminals, including Nazi doctors who performed experiments on concentration-camp prisoners

- Twenty-three persons including **20 doctors were tried; 15 were found guilty; 7 were sentenced to death**

- The tribunal developed a code of conduct for researchers, the *Nuremberg Code*, a 10-point statement outlining permissible medical experimentation on human participants

1966: Henry K. Beecher's Article - 1

- Beecher was a very prominent faculty and Professor of Anesthesiology at Harvard Medical School, USA.
- In 1966, he published an article in the New England Journal of Medicine which became one of the most important landmarks in research ethics.
- His article described 22 researches in which patients never had the risk associated with the research satisfactorily explain to them although they suffered grave consequences.

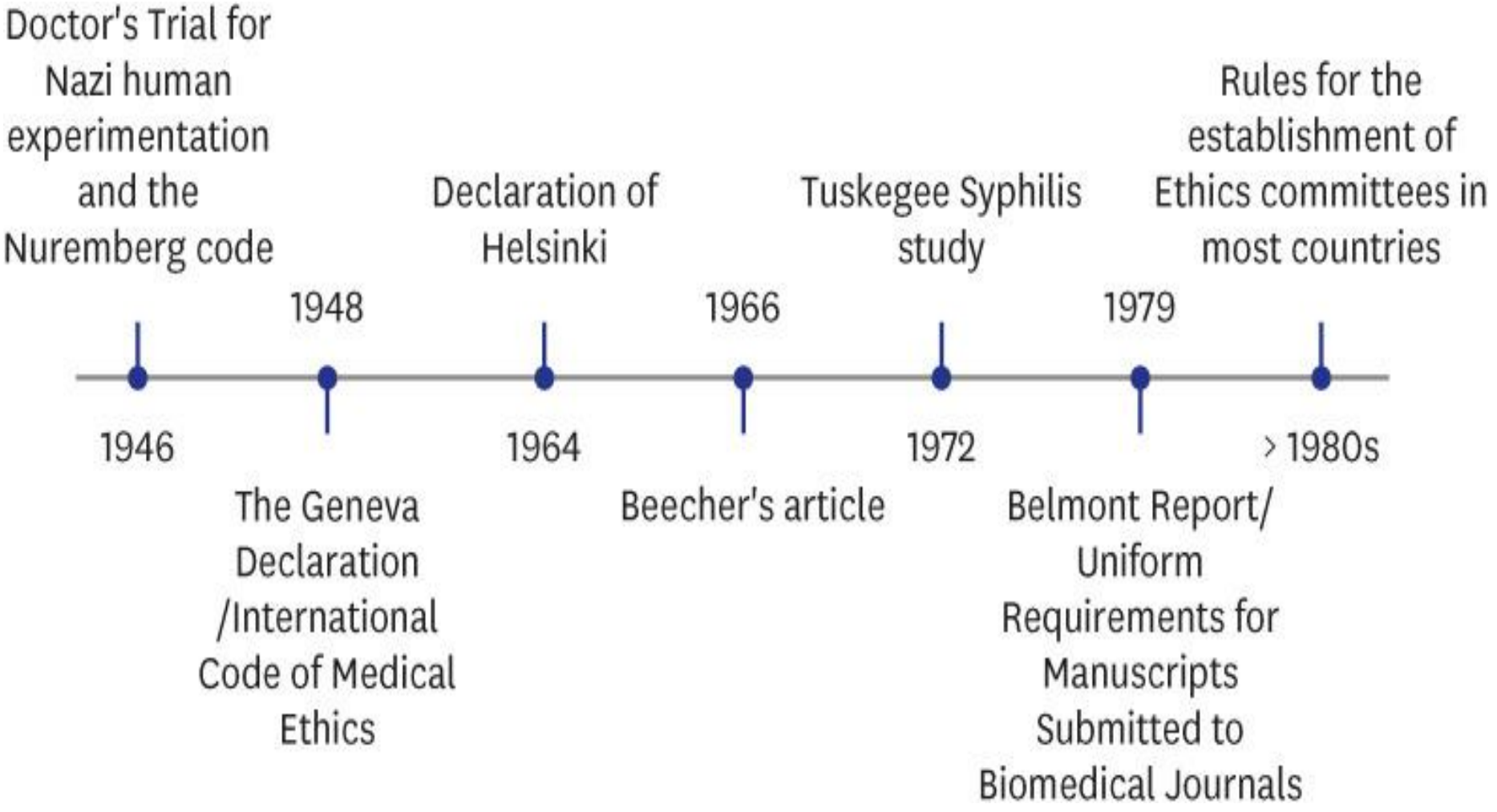
1966: Henry K. Beecher's Article - 2

- Studies included withholding antibiotics from men with rheumatic fever, purposely infecting institutionalized children with hepatitis (Willowbrook), injecting live cancer cells into nursing home patients (Jewish Chronic Disease Hospital).
- The paper showed that abuses and exploitations of humans in research continued despite codes of ethics.
- This paper started the modern research bioethics movement in the U.S.

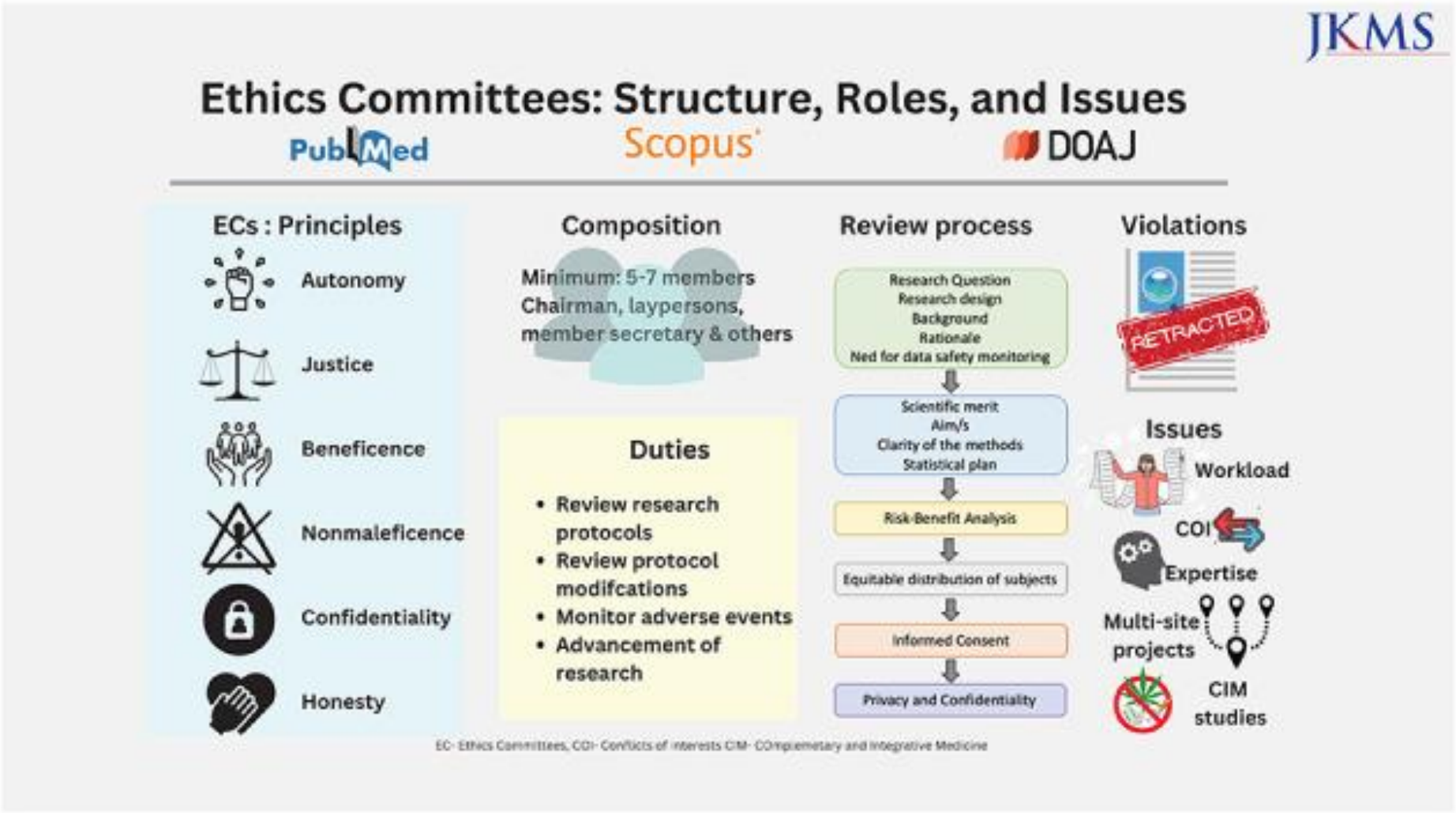
Advent of Institutional structures for submission of protocols for ethical conduct of Research

- The need for institutionalized mechanisms for human research participant protection was heightened following the public outcry over the Nuremberg trials
- Earliest HRECs –
  - ✓ NIH (restricted) 1953
  - ✓ Extended in 1966 to all extramural research supported by USPHS
  - ✓ 1967 the Royal College of Physicians statement that research should be subject to ethical review
- Yet no formal legislations/guidelines at the time

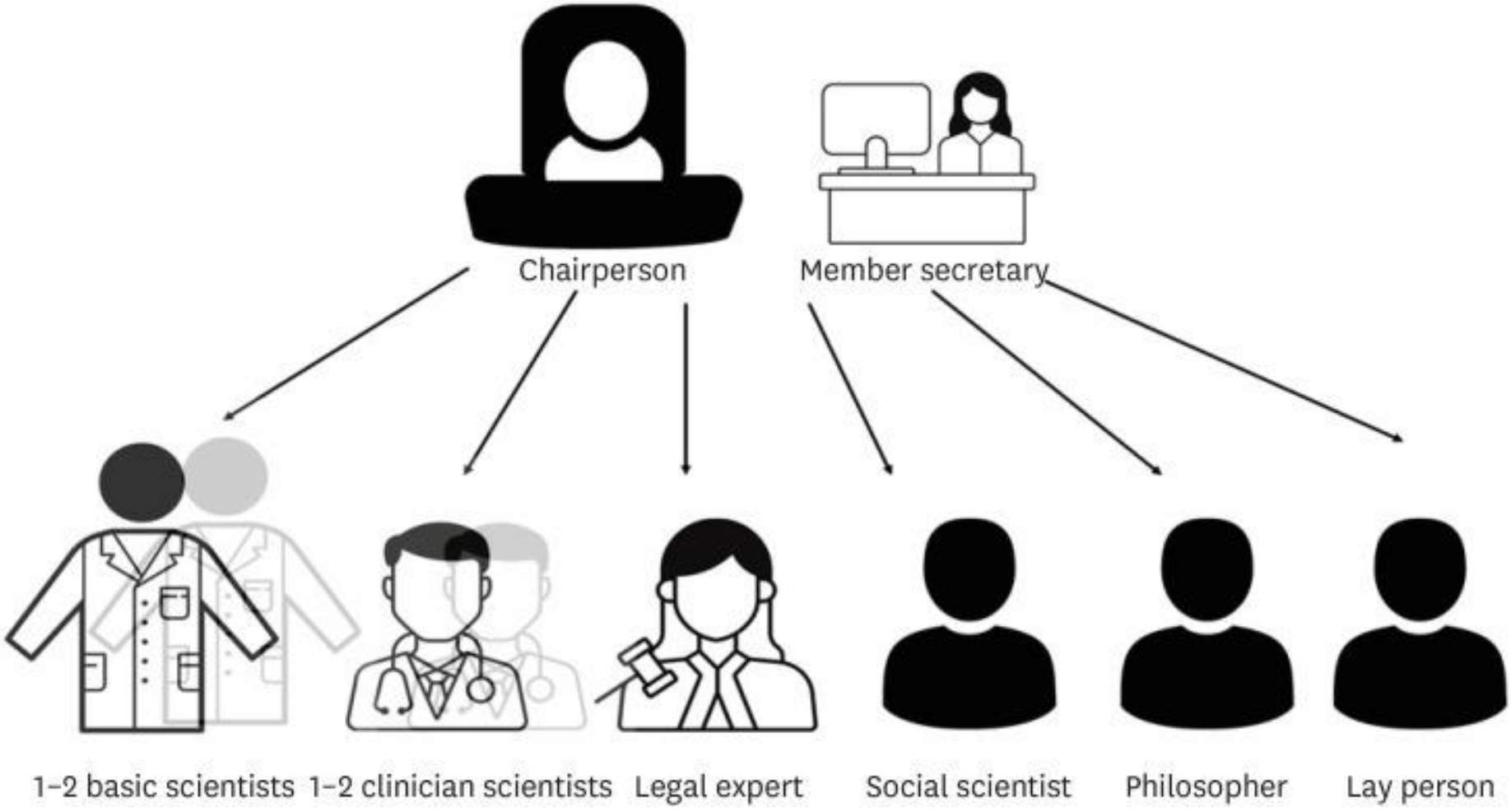
Timelines of events that led to the establishment of Institutional structures-Ethics Committees-1



Institutional structures -2



Institutional structures – Research Ethics Committee-3



Institutional structures -4

- Responsible researchers must submit and obtain approval of study protocol from an accredited Ethics Review Committee (ERC) before commencement of research
- An efficient ERC should review both **the science and the ethics** of the proposed research
- Responsible researchers avoid plagiarism in the development of their study protocol
- There must be demonstration of integrity by both researchers and the RECs using NCHRE and other international ethics codes as a guide.

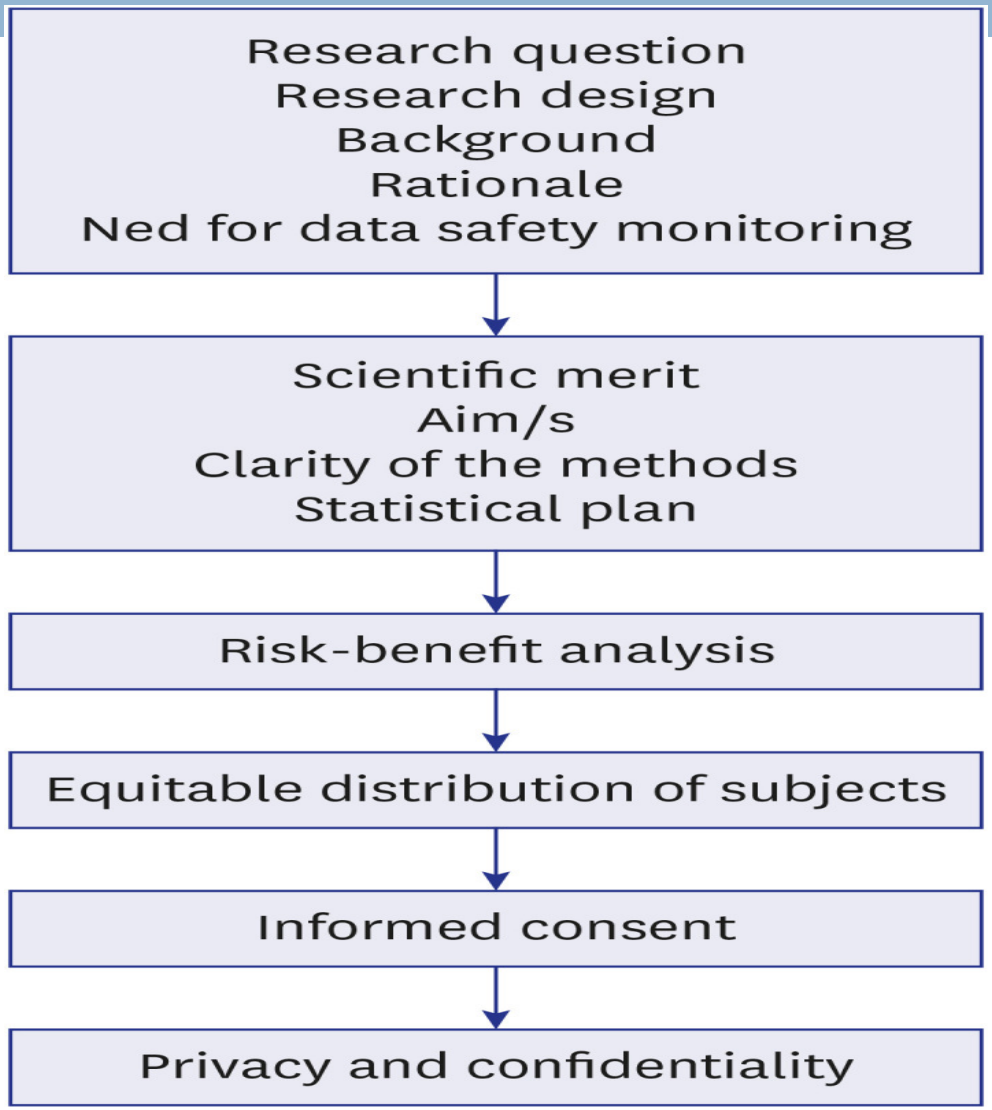
Institutional structure -5

- These institutional structures (the Ethics committees) are formed to contribute to safeguarding the rights, safety and well being of actual and potential research participants
- They help to reassure society that independent review of research has occurred
- They help reduce the risk in any research by assessing the risks and benefits independently and conflicts of interests resolved
- They are called different names in different countries and jurisdictions but the essential functions are the same.
- REC, IEC, IRB, ERC, etc

Institutional structure-6 (Legitimacy and Legal status)

- Ethics committees over the world have evolved as a result of genuine concern of a collection of the people who believe it was important towards improving the integrity of research practice in their institutions and/or countries
- And later as a result of this legitimacy, laws were enacted to further enhance their mandates
- It has thus been argued that even without extant laws, the establishment of ethics committees are seen as legitimate initiatives for research governance
- Though the ethics committees of some countries have not been established by statutory laws
- In Nigeria, ethics committees have been legitimized by the National Health Act of 2014: National Health Act, 2014 (8): Part IV, **A158-A160**

Institutional structure -7:The factors assessed in the process of review of a study by an Ethics Committee



Institutional structure-8: Ethical considerations

- ***Essentiality of the Research***
- ***Maximization of public interest and social justice***
- ***Knowledge, ability and commitment to do research***
- ***Respect and protection of autonomy, rights and dignity of participants***
- ***Privacy, anonymity and confidentiality***
- ***Precaution and risk minimization***
- ***Non-exploitation of participants***

Institutional structure-9: Ethical considerations

- ***Publication of Research in Public domain***
- ***Accountability and transparency***
- ***Totality of responsibility***

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Ten questions the REC will ask in international collaborative protocols

- Is there anybody designated as the local principal investigator (PI)?
- What is the PI's relationship with the community from which the research volunteers will be recruited?
- Does the research protocol address the ethical challenges of conducting research in a developing country?

?Ten questions- REC-2

- Is the purpose of the research responding to the health needs of the host country?
- How will the investigators ensure free and voluntary informed consent process
- Are the risks to volunteers acceptable in the social context of the host country?
- What exactly is the local standard of medical care?

?Ten questions-REC-3

- Does anyone else such as regulatory agencies in the host country know about the research?
- Is capacity building an essential element in the research protocol?
- What public health actions will result from the findings of the research study

Benefits of review

1. Helpful and constructive criticisms that will improve the research methodology to ensure that the study is of value to society
2. Identify potential for abuse of research participants through the review of recruitment procedures and the informed consent process
3. Raise concerns if the research is being conducted among vulnerable population so that the bar for safety standards is raised
4. Identify potential for scientific misconduct such as plagiarism

Approval by an ERC is increasingly becoming an important requirement for publication of research findings in some journals

Challenges

1. Lack of competence of reviewers
2. Review of non-essential components (grammar, punctuations, typographical mistakes)
3. Delay in commencement of research
4. Researchers do not belief in value of review of protocol
5. Request for retrospective review of protocols
6. Research continue to take place without review
7. Lack of resources (money, staff, equipment) to run an ERC especially in developing countries

Perception of the roles of REC

Some interventions

- Initial and continue education of members of REC and researchers
- Committees should expedite the process of review (especially students' application)
  - Need to provide some incentives for reviewers to fast track process of review
  - Create additional committees in large institutions with heavy workload
  - Hire professional staff whose primary function is review of protocols
  - ✓ **In spite of challenges review is of benefit to researchers, participants, institutions & science**

The document - NCHRE

National Code of Health Research Ethics

2006

National Health Research Ethics Committee of Nigeria (NHREC)

FEDERAL MINISTRY OF HEALTH

DEPARTMENT OF HEALTH PLANNING AND RESEARCH

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National Code for health research (NCHRE)?

- NCHRE is the document published by NHREC to set the norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials in Nigeria
- This can be accessed on the NHREC website: www.nhrec.gov.ng

NCHRE

- Every researcher must comply with the regulations in the National code for health research ethics (NCHRE) in the conduct of ethical research in Nigeria
- NCHRE should be embraced by all HRECs in Nigeria
- We can also contribute to the development and review of the code

Ethics Committees System in Nigeria-1

- The UI/UCH HREC is arguably the oldest one in Nigeria, established in 1981
- Other similar HRECs were established in the 80's, 90's, with most established only in the last decade
- Evolved in fulfillment of requirement for research investment by institutions from developed countries
- Quite a number never lasted beyond the lifetime of such funding

Ethics Committees System in Nigeria-2

- Around the same time in the 80's, a National Ethics and Review Committee had been in place at the Federal Ministry of Health
- Most reviews were however channeled to NIMR
- Following renewed concerns over allegations of unethical research and in recognition of increasing research investments, the Hon. Minister of Health, reconstituted and inaugurated the National Health Research Ethics Committee (NHREC) in 2006

Ethics Committees System in Nigeria - 3

- NHREC mandates contained in the National Health Law-
- The Law provided for a National Committee and mandates all research active institutions to have local HRECs
- The National Code for Health Research Ethics, developed by NHREC spells out the ethics committee system and the functions of HRECs in Nigeria

The National Health Act 2014

Federal Republic of Nigeria
Official Gazette

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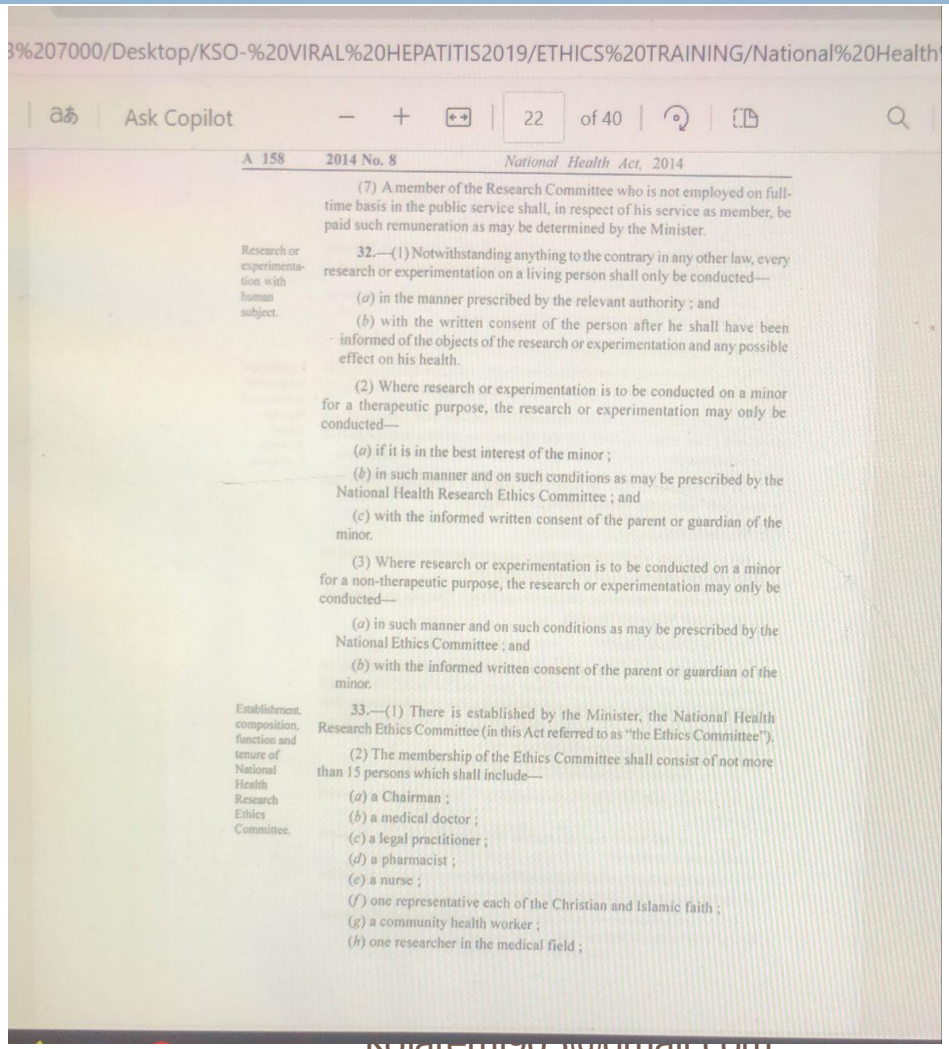
NHA (2014) Section A158 no.8



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A 158 2014 No. 8 *National Health Act, 2014*

(7) A member of the Research Committee who is not employed on full-time basis in the public service shall, in respect of his service as member, be paid such remuneration as may be determined by the Minister.

Research or experimentation with human subject.

32.—(1) Notwithstanding anything to the contrary in any other law, every research or experimentation on a living person shall only be conducted—

(*a*) in the manner prescribed by the relevant authority ; and

(*b*) with the written consent of the person after he shall have been informed of the objects of the research or experimentation and any possible effect on his health.

(2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted—

(*a*) if it is in the best interest of the minor ;

(*b*) in such manner and on such conditions as may be prescribed by the National Health Research Ethics Committee ; and

(*c*) with the informed written consent of the parent or guardian of the minor.

(3) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted—

(*a*) in such manner and on such conditions as may be prescribed by the National Ethics Committee ; and

(*b*) with the informed written consent of the parent or guardian of the minor.

Establishment, composition, function and tenure of National Health Research Ethics Committee.

33.—(1) There is established by the Minister, the National Health Research Ethics Committee (in this Act referred to as "the Ethics Committee").

(2) The membership of the Ethics Committee shall consist of not more than 15 persons which shall include—

(*a*) a Chairman ;

(*b*) a medical doctor ;

(*c*) a legal practitioner ;

(*d*) a pharmacist ;

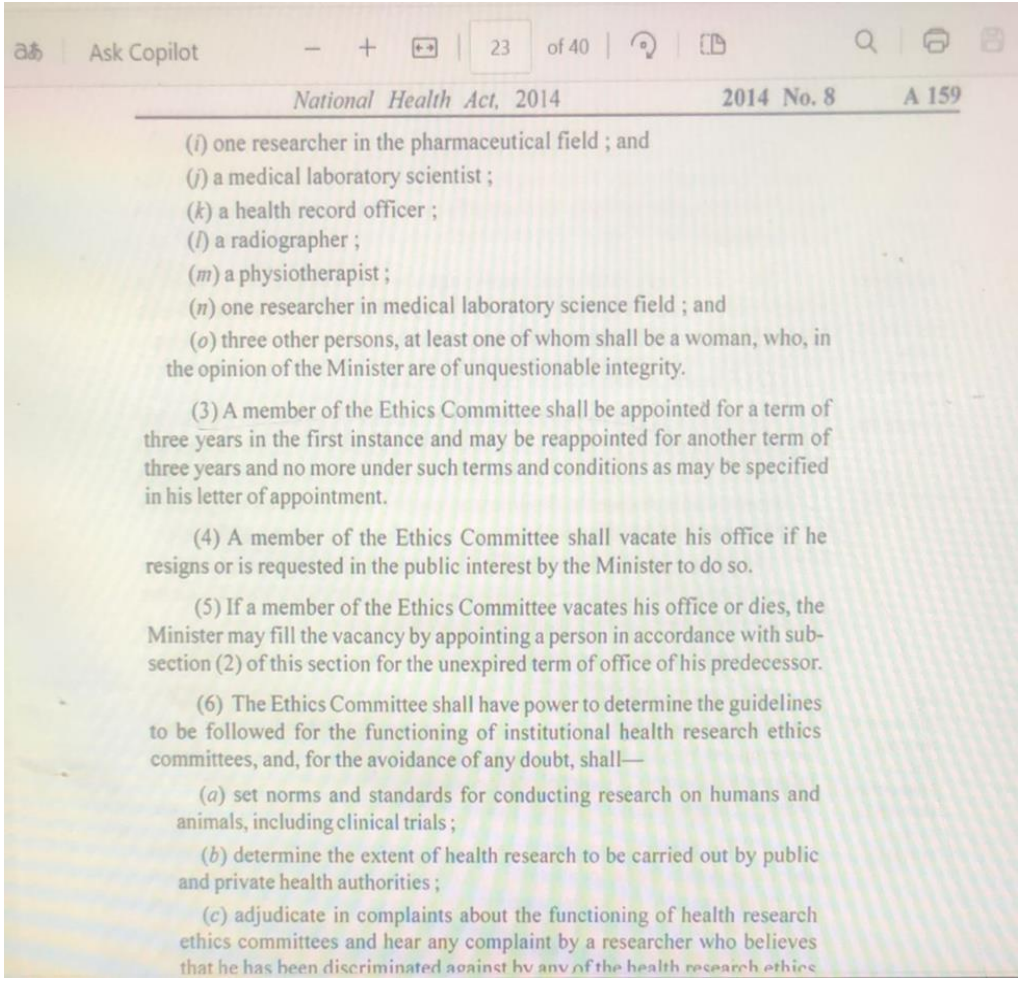
(*e*) a nurse ;

(*f*) one representative each of the Christian and Islamic faith ;

(*g*) a community health worker ;

(*h*) one researcher in the medical field ;

NHA (2014):Section A159 no.8



(*i*) one researcher in the pharmaceutical field ; and

(*j*) a medical laboratory scientist ;

(*k*) a health record officer ;

(*l*) a radiographer ;

(*m*) a physiotherapist ;

(*n*) one researcher in medical laboratory science field ; and

(*o*) three other persons, at least one of whom shall be a woman, who, in the opinion of the Minister are of unquestionable integrity.

(3) A member of the Ethics Committee shall be appointed for a term of three years in the first instance and may be reappointed for another term of three years and no more under such terms and conditions as may be specified in his letter of appointment.

(4) A member of the Ethics Committee shall vacate his office if he resigns or is requested in the public interest by the Minister to do so.

(5) If a member of the Ethics Committee vacates his office or dies, the Minister may fill the vacancy by appointing a person in accordance with sub-section (2) of this section for the unexpired term of office of his predecessor.

(6) The Ethics Committee shall have power to determine the guidelines to be followed for the functioning of institutional health research ethics committees, and, for the avoidance of any doubt, shall—

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

(*b*) determine the extent of health research to be carried out by public and private health authorities ;

(*c*) 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

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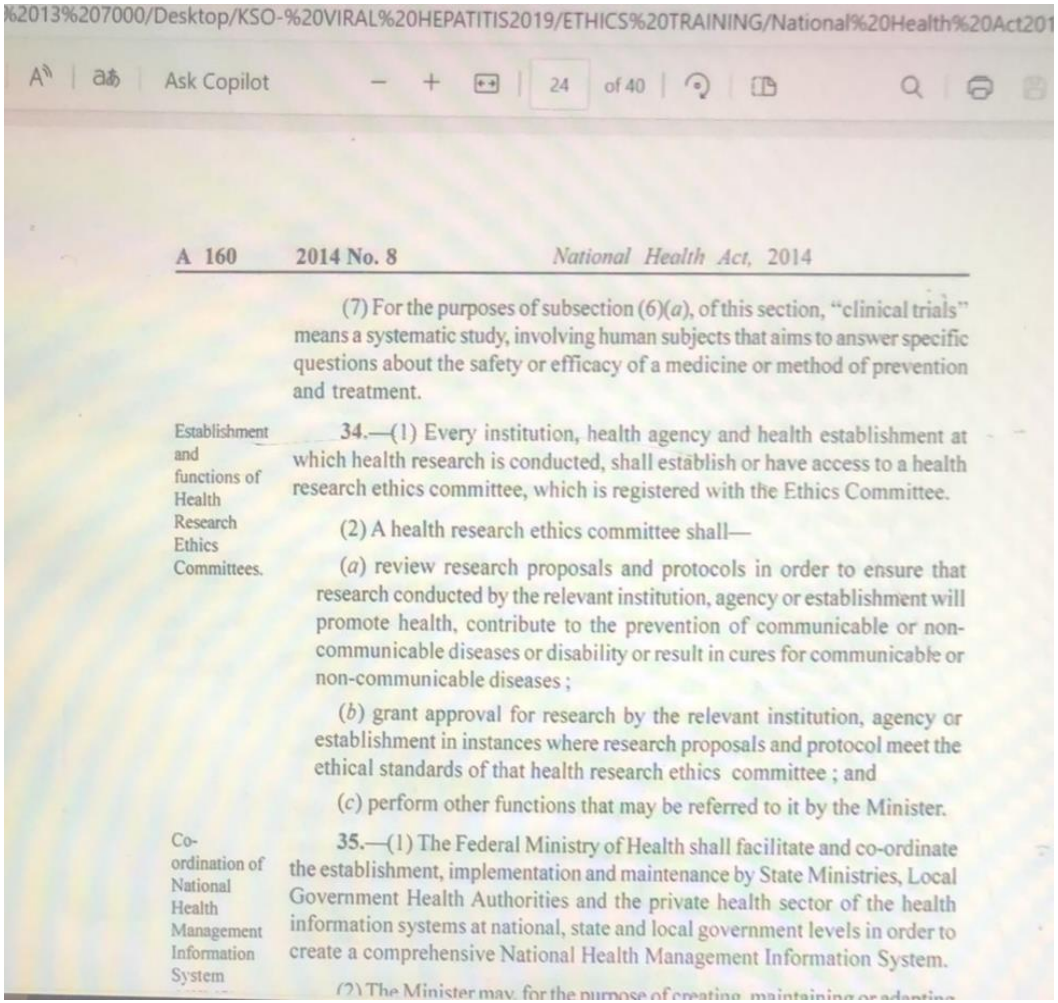
NHA (2014):Section A160 no.8



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A 160 2014 No. 8 *National Health Act*, 2014

(7) For the purposes of subsection (6)(*a*), of this section, "clinical trials" means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of prevention and treatment.

Establishment and functions of Health Research Ethics Committees.

34.—(1) Every institution, health agency and health establishment at which health research is conducted, shall establish or have access to a health research ethics committee, which is registered with the Ethics Committee.

(2) A health research ethics committee shall—

(*a*) 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 ;

(*b*) 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 ; and

(*c*) perform other functions that may be referred to it by the Minister.

Co-ordination of National Health Management Information System

35.—(1) The Federal Ministry of Health shall facilitate and co-ordinate the establishment, implementation and maintenance by State Ministries, Local Government Health Authorities and the private health sector of the health information systems at national, state and local government levels in order to create a comprehensive National Health Management Information System.

(2) The Minister may, for the purpose of creating, maintaining or adapting

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Are there still unethical practices?

Yes, yes, yes and yes

- Not seeking informed consent from study participants
- Asking research participants to pay for research
- Conducting research without ethics approval
- Conducting research that is not of benefit to study participants

Important Links

- Guidelines for submitting applications for ethics review:

https://nhrec.net/nhrec/Ethics_committee_Protocol_submission_guidelines.pdf

- Registered ethics committee in Nigeria: https://nhrec.net/registered-health-research-ethics-committees-in-nigeria-hrec
- National Health Act 2014: https://p4h.world/en/documents/national-health-act-2014/

Conclusion

- The intimate relationship between research and ethics is unequivocal, and the contribution of ethical perspective, particularly in the conduct of ethical research is invaluable.
- Identifying the challenges emanating from obtaining valuable data without prior ethics approval will assist the investigators/researchers in making proper decisions on implementation of Best practice in the conduct of ethical research among their citizens.
- Communication, transparency and updates are crucial factors in the ethical considerations and conduct of ethical research

THANK YOU FOR LISTENING !!!