

Regulatory Authorities- Zambian Perspective

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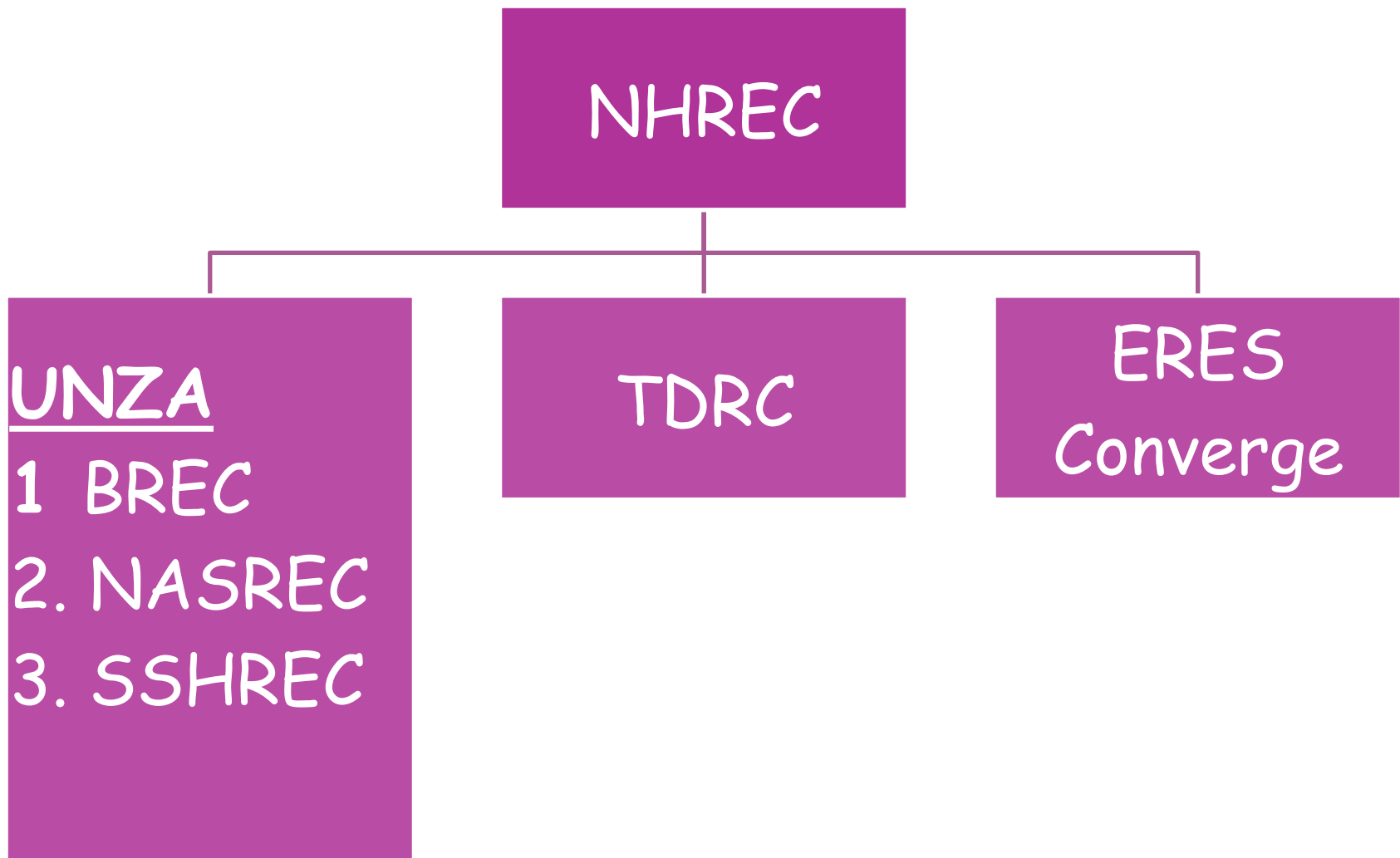
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Outline

- Organisation of RECs
- History & Organisation of UNZABREC
- History and Organisation of TDRC-REC
- National Health Research Advisory Committee (NHRAC)
- National Health Research Ethics Committee (NHREC)
- National Health Research Bill
- Summary

Organization of RECs



UNZABREC History 1/3

Has been in existence since the early 1980s (at the advent of HIV)

Borne out of the concern of researchers (mainly from the School of Medicine) over the burgeoning research in the area of HIV and AIDS

UNZABREC History 2/3

Reconstituted in 2001

- SOPs Developed

Secretariat comprising:

- Chairperson,
- Secretary (now Vice-Chair) and
- Administrative Secretary

UNZABREC History 3/3

- Reviews all types of research proposals involving human participants (and vertebrate animals)
- Independence and competence are its two hallmarks.

Membership 1/4

- Members of the Committee (inclusive of the Secretariat) are appointed by the Vice-Chancellor of the University of Zambia on the recommendation of the Dean of the School of Medicine.

Membership 2/4

Membership includes individuals with:

- **varying backgrounds**
- **possession of appropriate professional competencies**

to review the diverse types of protocols that are received.

Membership 3/4

- 12 members
- School of Medicine representative
- UTH representative
- Basic medical scientists
- Clinicians (Medical and Veterinary)
- Social Scientist/Biostatistician/Epidemiologist
- Ministry of Health Representative
- Legal expert
- Philosopher/Theologian/Bioethicist
- Community Representative

Membership 4/4

- The duration of appointment is for a period of 3 years

TDRC-ERC

TDRC-ERC

- TDRC Statutory body formed by an act of Parliament

TDRC-ERC

- Located in Ndola on the Copperbelt of Zambia
- Established in the 70s
- 2-tier review system
 - Scientific Technical Committee (STC)
 - Ethics Review Committee (ERC)

TDRC-ERC: Secretariat

- Chair
- Secretary to Committee
- Administrative Secretary

TDRC-ERC: Membership

- 8 members with diverse backgrounds
 - Paediatrician
 - Physician
 - Lawyer
 - Clinician
 - Scientist
 - Retired nurse
 - 2 senior citizens (male & female)

TDRC-ERC: Membership

- Chair appointed by the Minister on recommendation by the Board
- Members appointed by the Board

National Health Research Advisory Committee (NHRAC)

- provide oversight and coordination of health research;
- develop and review mechanisms for setting national health research priorities and strategies in light of the health research needs of Zambia;

National Health Research Advisory Committee (NHRAC)

- harmonize, network and promote partnerships in health research;
- advise the government on all matters related to health research
- promote translation of health research outcomes into policy decision making;

National Health Research Ethics Committee (NHREC)

- Regulates human and animal research ethics in the country.
- Provides oversight and ensures adherence to guidelines that govern research practice in Zambia.

Legal Framework Background

- Until 2010 no specific legal framework providing for the operation of RECs in Zambia
- “Borrowed” from existing pieces of legislation e.g.
 1. Human Tissue Act CAP306.
 2. University Act no 22 of 1992
 3. Science and Technology Act no 26 of 1997

Triggers

- Researchers questioning REC Mandate
- Uncontrolled/illegal exportation of samples by researchers
- Riots in Mazabuka following release of MDP 301 Microbicide Trial results

NATIONAL HEALTH RESEARCH BILL 2011

- A bill to provide a framework for *development, regulation, financing* and *coordination* of health research involving:
 - human participants,
 - biological material transfer,
 - clinical trials,
 - traditional complementary and alternative medicines,
 - data management,
 - dissemination,
 - priority setting and partnerships,
 - human resource development,
 - intellectual property rights;

NATIONAL HEALTH RESEARCH BILL 2011

- to provide for the establishment, powers and functions of the *National Health Research Authority of Zambia* and to provide for matters connected with or incidental to the foregoing.

National Health Research Act 2011

- This Act may be cited as the National Health Research Act 2011 and shall come into operation on such date as the Minister may by statutory instrument, appoint.

Application

- This ACT applies to all health research involving human participants and vertebrate animals in Zambia.

NATIONAL HEALTH RESEARCH AUTHORITY OF ZAMBIA

The Authority shall have the following functions:

- provide oversight and coordination of health research;
- develop and review mechanisms for setting national health research priorities and strategies in light of the health research needs of Zambia;
- maintain a database of studies and facilitate the dissemination of research results;
- harmonize, network and promote partnerships in health research;
- regulate the conduct of health research by individuals and organizations;

NATIONAL HEALTH RESEARCH AUTHORITY OF ZAMBIA

- accredit health research institutions;
- mobilize and disburse resources for health research activities;
- Facilitate the development of health research capacity of individuals, institutions and systems;
- promote translation of health research outcomes into policy decision making;
- advocate for health research within society, government and private sectors;
- advise the government on all matters related to health research;

National Health Research Authority of Zambia

- recommend to the law enforcement authorities for prosecution of individuals and institutions that contravene the provisions of this Act;
- investigate reports of health research misconduct and report professional misconduct to relevant professional bodies;
- maintain a profile of non complying individuals or institutions;
- develop and review accreditation guidelines for health research institutions;
- promote collaboration with similar organizations outside Zambia; and
- do all such things as are connected with or incidental to the functions of the Authority under this Act.

Powers of the Authority

- (a) withdraw accreditation for a health research institution;
- (b) ban researchers;
- (c) stop an on-going research;
- (d) impose a fine;
- (e) inspect any institution or research site conducting health research including data bases and biobanks;

Powers of the Authority

- (f) confiscate, impound, and destroy where necessary biological materials obtained by any person who contravenes any part of this Act;
- (g) require any health researcher or health research institution to submit such information and records as may be necessary to enable the authority to monitor the performance of such a health researcher or health research institution;

Powers of the Authority

- (h) consider any matter relating to health research and make representations thereon to the Minister; and
- (i) to require any health researcher who is in control of a health research activity to inform the authority of the intention to move from the registered premises prior to relocating.

Part III

13. Health Research on or Experimentation with Human Participants
14. Prohibition of therapeutic and reproductive cloning of human beings
15. Removal of tissue, organs, blood, blood products or gametes from living persons for research purposes
16. Prioritisation of health research

Part III

17. Dissemination of health research

18. Ownership, deposition and access of health research data sets

19. Monitoring and evaluation

20. Partnerships in health research

Part IV

21-27 NATIONAL HEALTH RESEARCH ETHICS (NHREC)

- Functions of NHREC
- Composition of NHREC
- Term of Office
- Offences and Penalties

Part V

28- 33 Biological Materials for Research

- Collection
- Storage
- Exportation
- Ownership

Part VI

34- Clinical Trials

Part VII

35. Research in Traditional Complementary and Alternative Medicine

Part VIII

36. Intellectual Property Rights

Part IX

37- 40 Financing (of the Authority)

Part X

41. Financial provisions for Health research

Part XI

42-44 General Provisions

- Regulations
- Immunity
- Jurisdiction over offences committed outside Zambia

45. Code of Ethics for Researchers

46. Appeals to Courts of Law

47-51 Transitional Provisions

Clinical Trials

- Parallel application to REC & Pharmaceutical Regulatory Authority (PRA) as prescribed in the Pharmaceutical ACT No. 14 of 2004, Part VII.

Summary

- Regulatory framework still being developed
- Most functions currently undertaken by RECs
- Need to network and draw from experiences by other countries in the region

Zikomo!
Thank You!