Processes and Procedures for Research Ethics

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Topics To Be Discussed

1. Regulatory framework of RECs – DoH, 2015 - NHREC
2. How to Prep for NHREC Annual Report
3. REC Admin Challenges
4. Document Management

INTRODUCTION

Research Ethics (RE)?

Research ethics **guides** us on how scientific research should be **conducted** and **disseminated**.

Why

Cause of unethical research studies which occurred.

In the 20th century, ethical guidelines were developed.

Tuskegee Study

Dr Werner Bezwoda

VIOLATION OF ETHICAL STANDARDS

ETHICAL PRINCIPLES

Systems started to be put in place

Nuremberg Code, Food, Drug, and Cosmetic Acts, Declaration of Helsinki, The Belmont Report ----, DoH – Ethics in Health Research: Principles, Processes, and Structures (2004, 2015)

Beneficence - DO GOOD

Non-maleficence – DO NOT HARM

Autonomy – A PERSON'S FREEDOM OF THOUGHT & ACTION SHOULD BE RESPECTED

Justice – BALANCE RISKS AND HARM

Benefit future generations.

Researchers are expected to adhere to these principles.

NHREC Guideline

- **Regulatory Authority** – NHREC was established in 2006 in terms of *s* 72 of the National Health Act

The NHA (s 72(1)) requires that proposals to conduct 'health research' must undergo an independent ethics review before the research is commenced.

Ethics review of proposed 'health research' must be conducted by a REC or AREC registered with the NHREC.

The review must ensure that ethical and scientific standards are maintained to
- Protect participants from harm - HOW
- Protect the safety and welfare of animals used in research by ensuring close adherence to the expected benchmarks

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NHREC Guideline

Researchers accountable for the research activities – **Research Integrity comes in -** Research misconduct - Fabrication, Falsification & Plagiarism

Challenge – lack of monitoring, and no capacity

Type of proposal – Emanuel et al, 2004 – unifies and brings consistent ethical guidance:8 principles – collaborative partnerships, scientific validity (proposals be well designed), social value, a fair selection of participants (exclusion and inclusion), risk-benefit ratio, independent review, informed consent (KII, FGDs) ongoing respect for participants and study communities (confidentiality, research reports)

ROLE OF RESEARCH ETHICS COMMITTEES

The primary role of the REC is to protect the interests (rights and welfare) of the research participants who volunteer to take part in scientifically sound research.

NHREC Guideline

Terms of Reference and Standard Operating Procedures

Each REC should have Terms of Reference (ToR) and Standard Operating Procedures (SOPs).

The ToR should include the scope of the REC's responsibilities, its relationship to non-affiliated researchers (external applicants), its accountability responsibilities, the mechanisms for reporting and remuneration, if any, for members.

The SOPs set out in systematic detail.

Code of Conduct

The institution should have a Code of Conduct for REC members, which details the conduct and integrity expectations of REC members.

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NHREC Guideline

Membership

Membership should include

- As many disciplines, sectors, and professions as possible appropriate to the responsibility of the particular REC. Members are drawn not only from the senior ranks, ethnically and culturally diverse, a mix of males and females, and lay persons (community reps)

Research Ethics Committees

All REC members should have proof of research ethics training, refreshed at least once within the appointment period.

REC membership should consist of - at least nine members, one layperson, medical practitioner, psychologist, social worker, or nurse with experience in qualitative research methodologies, bio-statistics, expertise in research ethics, and one legally qualified member.

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NHREC Annual Report

Submission date – **END of February 2023**

How do you prepare for annual submissions?

Protocol Tracking sheet – Track all the protocols using spreadsheets
- Use the NHREC annual report to prepare the spreadsheet/tracking sheet

Online System

Document Management

- **Confidential** – sign a confidentiality agreement
- Minutes
- Research Protocols
- How long do you keep documents? 5 years – POPIA
- Then, after 5 years what happens? Discard / <u>Archive</u>?

THANK YOU!