Equipping the NWU REC Administrators on key responsibilities, processes, and best practices ensuring the practical and ethical review of research protocols within the NWU research environment

North-West University (NWU)
23 February 2024

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Getting to know you !

- My name is [_____], the story behind the meaning of my name [_____]
- What is it that you do [_____], and the level of experience with research ethics [_____]
- What is one thing that you would like to take home from this session [_____] ?

And that is my beautiful story ☺

Content

- Why research ethics is important?
- Laws governing research ethics in South Africa (NHREC)
- NHREC audit
- Research Policies
- Role Players
- Audit requirements
- Standard Operating Procedures
- Terms of Reference
- Joining COPs institutions of higher education

Why research ethics is important?

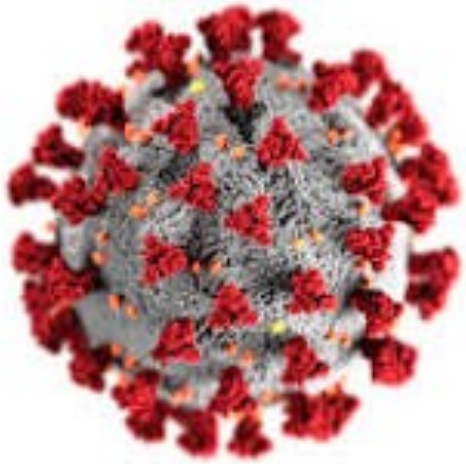
A bit of history !

The intensive development of research ethics requirements can be traced back to the Twentieth Century – a period, which witnessed a sudden surge in the amount of human research being conducted globally.

Without an understanding of the historical context, it is very difficult for one to understand the sense and need for research ethics, more so its development over the past decades to become one of the formal requirements for research.

Regrettably, most of the grave abuses of human beings in research occurred in the area of medical research where research ethics was born.

A bit of history cont...



Cases of abuse reported in Africa :

- Dr. Richard Gladwell McGown case – Zimbabwe

- These known cases of unethical research practice in Africa, the clinical trials that were conducted in Africa during the 1900s have led to some serious debates regarding comparative standards of research ethics in Africa and so-called first-world countries.
- The above-mentioned examples are but a few of the many that indicate that, without a robust research oversight system, researchers and research staff might disregard ethical principles, national laws and international guidelines, either inadvertently or deliberately.

The difference between research ethics and laws

- Law and ethics are not the same things, although they can overlap. What is demanded or forbidden by law may not be by ethical standards.
- Research ethics can be defined as norms for conduct that distinguish between acceptable and unacceptable behaviours in research. Research ethics is about the rights and wrongs in research, values of science and expected standards of conduct in science.
- Many people use the terms ethics and morality interchangeably as they both have to do with the right or wrongness of an action. The difference between morality and ethics is that morality is something that's normative, while ethics defines standards or rules that determine what is "good and bad" for a particular community, group, organisation or social setting.

Governance of research ethics in South Africa

- The National Health Research Ethics Council (NHREC) is a statutory body established under the National Health Act No 61 of 2003. The Act mandates the Minister of Health to establish the Council and it sets out NHREC's functions, which in short involve giving direction on ethical issues relating to health and developing guidelines for the conduct of research involving humans and animals. The council meets annually with all REC chairs to discuss developments or challenges within their institutions.

Governance of research ethics in South Africa cont...

- The National Health Research Ethics Council (NHREC) is tasked to oversee all University Research Ethics Committees and other organizations conducting research.
- They must all be audited and registered with the council in order to be able to review applications and give approval. The NHREC uses the 2015 & updated 2024 draft Guidelines for auditing.
- Based on the latest stats from the NHREC website there are 46 Human RECs and 21 Animal RECs registered with the council which makes a total of 64 RECs in South Africa. The number is still growing as more universities are coming on board.
- The current Chairperson is Prof Mello Sechoacha, who is an Associate Professor in the Department of Pharmacology in the Faculty of Health Sciences and an advisory member in the Senate Research Ethics Committee of the UFS.

National Health Research Ethics Council
NHREC

NHREC Guidelines

- DoH 2004 – National Health Research Ethics Council (2004) **Ethics in Health Research Principles, Structures and Processes**. National Department of Heath of the Republic of South Africa. Pretoria: NDoH.67p.ISBN: 1-920031-0409

- DoH 2015 – National Health Research Ethics Council (2015) **Ethics in Health Research Principles, Processes and Structures 2nd ed**. National Department of Heath of the Republic of South Africa. Pretoria: NDoH. 94p

- DoH 2024 (Draft) – National Health Research Ethics Council (2024) **South African Ethics in Health Research Guidelines: Principles, Processes and Structures 3rd ed**. National Department of Heath of the Republic of South Africa. Pretoria: NDoH.

SA's Research Ethics Guidelines

Research Ethics Committee (REC)

- Human Participant REC
- Animal Use REC
- Biomedical REC
- Environmental & Biosafety REC

SENATE / VC

- Reports submitted for noting
- Can advise the REC
- Does NOT have any statutory power over REC

NHREC

- Audits/Registration the REC
- REC submits annual progress reports
- Can override the REC decision
- Can dissolve the REC

South African Medical Research Council Guidelines, 2019 http://www.mrc.ac.za/research/ethics/guideline-documents

Kruger, M., Ndebele, P., & Horn, L. (Eds.). (2014). Research ethics in Africa: A resource for research ethics committees. African Sun Media.

Dhai, A., & Stein, C. (2020). Consent in health research with incapacitated adults in a time of pandemic: The National Health Research Ethics Council needs to urgently reassess its guidelines. South African Journal of Bioethics and Law, 13(1), 1-5.

Key Role Players

- Research Ethics Administration
-  Research Ethics Committees (RECs)
-  Researchers
-  Communities / External Stakeholders

Key Role Players – Close Up

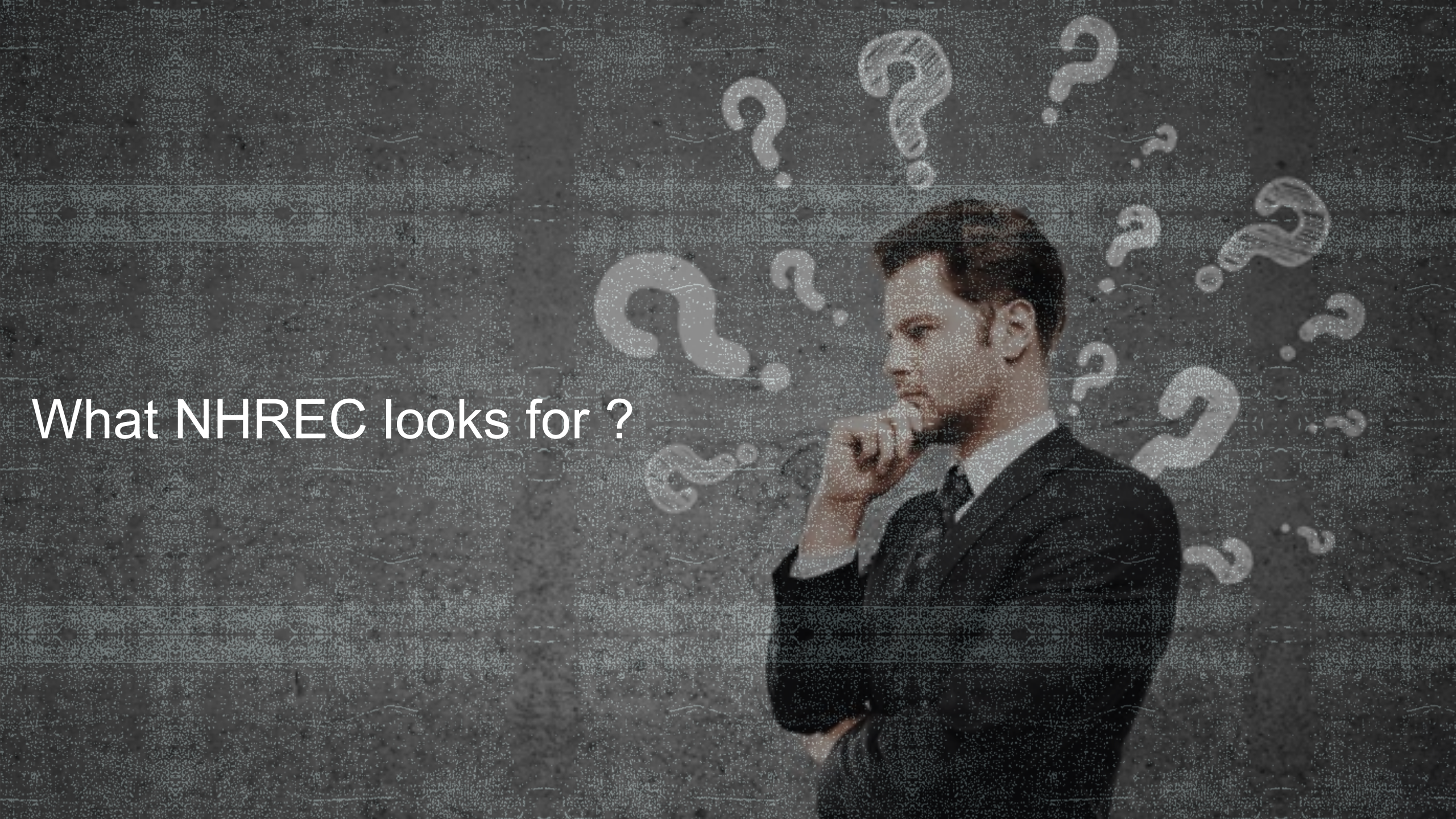
Research Ethics Administration	Chairs/Deputy Chairs Administrators/Officers/ Managers	Seniors Managers/Directors/DVC
Research Ethics Committees	Chairs/Deputy Chairs Administrators/Officers/ Managers	REC Members Online Systems
Researchers	Academic Staff Members Post-Doctoral Fellows	Postgraduate Students
Communities / External Stakeholders	Participants / Community Access	External Collaborators


TIME FOR
A BREAK!

AUDIT Process

- Invitation Letter
- Audit Process
- Attendees
- Required Documents : uploaded
- Dates and Deadlines

What NHREC looks for ?



Guiding Policy

A policy is a high-level governance or operational principle formally adopted by an institution

This policy must be :

- Updated according to the DoH guidelines
- Proof / Evidence that it has been approved to relevant structures
- Responsible person/office
- Date of approval and review

DoH 2024 (Draft) – National Health Research Ethics Council (2024) ***South African Ethics in Health Research Guidelines: Principles, Processes and Structures 3rd ed****. National Department of Heath of the Republic of South Africa. Pretoria: NDoH*

Membership

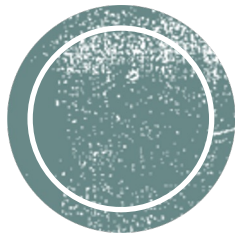
HREC

- Professional Care
- Expertise in qualitative or quantitative methodologies
- Lay / Community member
- Expertise in bio-statistics
- expertise in research ethics
- Expertise in law

AREC categories

- A- Veterinarian
- Scientist with experience in the use of animals
- Animal Welfare Organization Rep
- Lay person - not involved in animal research

Induction of RECs



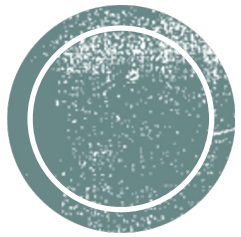
- Role of the ethics committee members
- Code of Conduct
- Expectations of integrity and confidentiality
- Responsibilities
- Management of Conflict of Interest
- Policy , SOP. TORs
- Meeting dates and reviews
- Legal framework

Evidence of ethics training

- ✓Dates of the training
- ✓Program of the training
- ✓Attendance register
- ✓Certification

Research Ethics processes – Submission by PI

Research Ethics processes



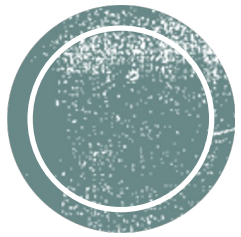
Application process depends on each university structure:

- Paper based application process (hand to hand)
- Online application systems (Converes, Oracle, RIMS, Infonetica)
- Workflow – *included on the website for transparency*
- Contact details/person
- Training (education)

Record Keeping and archives:

- Filing of applications or protocols
- Agenda, minutes and non-disclosure forms
- Attendance registers for meetings
- Membership
- Records of training

Research Ethics processes



Feedback and turn around time:

- Communication from administrators or secretariate
- Appeal process

Gatekeeper/Permission (GP) Letter:

- How GP letter works /Who is the GP?
- Not compulsory for all research

How to deal with amendment requests / annual progress report?

- Amendment requests during COVID-19 pandemic
- Annual progress reports for past monitoring and evaluation

Continuation of reviews

- **Active monitoring** – self-reporting independent onsite monitoring of research, typically involves active validation of compliance to ethical aspects of the approved protocol, including onsite observation of execution of the study.

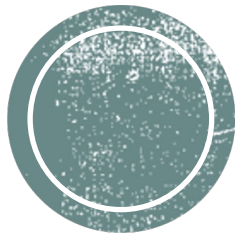
- **Passive monitoring** – self-reporting post-approval , monitoring of research, typically involves regular (minimum annually) written reporting by the PI about research involving human participants, including progress and problems encountered. Ensuring that the norm for period of approval is followed (12 months); that renewals must occur & be accompanied by a sufficient progress report.

NB: There must be SOPs and templates for the above

DoH 2024 (Draft) – National Health Research Ethics Council (2024) ***South African Ethics in Health Research Guidelines: Principles, Processes and Structures 3rd ed****. National Department of Heath of the Republic of South Africa. Pretoria: NDoH*

Compliance

Annual Progress Report – NHREC – 28th of February



- Membership changes
- Number of meetings held
- Number of applications or protocols presented, approved & rejected
- Monitoring or related matters
- Risks of protocols reviews
- Continuation or re-certification
- Study closure
- Adverse events and anticipation problems
- complaints received and actions taken

Audit – every after 5 years of the last audit (prior notification)

NB: There must be SOPs and templates for the above

Complaints

- A structure and process in place clearly stipulated in an SOP to deal with complaints queries and appeals about REC operations and decisions internally, before escalating matters to the NHREC.

- This also includes whistle-blowing SOPs as well in the promotion of research integrity

Data storage

- DOH National guidelines recommend 5-15 years for retention of records in accordance with institutional requirements
- HPCSA guidelines on Research states that All data including tape recordings should be stored for a minimum of 2 years after publication or 6 years if there is no publication.
- SAGCP Guidelines record in clinical research are to be retained for 15 yrs or until at least 2 years after the last approval of a marketing application and until there are no pending or contemplated marketing applications
- It is recommended that institutions and their RECs develop reasonable time frames for retention of their records

Institutional Capacity Development

- Budget
- Processes
- Research Ethics & Integrity promotion
- Trust – REC can operate independently

Standard Operating Procedures (SOPs)

- SOPs, describe how and when all the procedures and processes of the REC are to be carried out.

- The SOPs make it clear on what is expected. When this document is inadequate, the scope for non-compliance increases with the concomitant increase in risk of irregularities and ultimately reputational risk for the institution.

Required SOPs

- Active and Passive Monitoring - study continuation
- Complaints and Appeals
- Disclosure and Non-disclosure
- Quorum requirement
- The protocol review process
- Studies that do not involve Human or Animals
- Expedited and full committee reviews
- Decisional analysis guidance
- Risk Assessment
- Data Management
- Serious adverse events
- Whistleblowing

NB: All the above SOPs need templates to be used by researchers

Terms of Reference (ToR)

- ToR should be separated from SOPs. The former document establishes the legal basis for the existence of the REC; describes its reporting channels, its mandate; the scope of its authority, etc.

- ToR make it clear that the REC has authority and power

(see DoH 2015/2024 Guidelines & Annual Report template for more details)

Categories for approval by RECs

- **Approved** : This is a straight forward approval with no additional commence, data collection may start once ethical clearance certificate has been granted
- **Provisional approval** – this is an approval that does not allow the researcher to start with data collection until they receive permission/ gatekeeper approval
- **Approved in principle/ Approved with minor corrections/revisions** – this is approved but ethical clearance certificate will be issued by the chair administratively once the corrections have been dealt with
- **Not approved/ Not approved with major revisions** – the application may not proceed with data collection and resubmit for the next REC meeting for full consideration

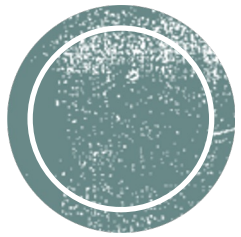
Gatekeeper (GKP)

- **A GATEKEEPER** is the high authority (or designee) of the organization or site at which your research activities will take place - such as a school principal, clinic director, department manager, club leader, university registrars, community leaders (induna/chief), religious leaders, municipal managers or program administrator

Letter to the gatekeeper

- Draft letter(s) to gatekeepers must be attached for review by the REC and for consideration by the GKP.
- Gatekeeper letters to be sent only after REC approval – provisional approval pending gatekeeper letter
- Sufficient information provided about the proposed research process for gatekeeper to make an informed decision?

Confidentiality of data



DOH, 2015 Guidelines describes:

- **Identifiable data**: name, date of birth, address hospital no., mobile no.
- **Potentially Identifiable data (coded re-identifiable data)**: identifiers removed and replaced with a code that can re-identify
- **De-identified Data (not re-identifiable and anonymous data):** all identifiers permanently removed and no codes used

Protection of Personal Information Act (POPIA)

- POPIA regulates processing of personal information in response to developments of measures to protect privacy. POPIA provides guidance on how personal information may be processed and participants privacy protect

- De-identify – in relation to the personal information of a data subject, means to delete any information that could be :

  a) Identifies the data subject

  b) Can be used or manipulated by a reasonably foreseeable method to identify the data subject

  c) Can be linked by a reasonably foreseeable method to other information that identifies the data subject

Training

- If members are not trained or if training is not up to date, the risk is that members do not know about developments in research ethics and other regulatory areas and this may affect the quality of reviews, which ultimately may pose a potential risk to participants and more unnecessary work for the Committee.
- Ensure that all REC members and researchers at least undertake online training, which includes an assessment component and produces a certificate.
- Educational forums and learning discussions are also encouraged for budget constraints

Administrative Support

- **Administrative support for REC:**

- Inadequate resourcing for administrative support of the RECs of the institution holds out the risk that the system becomes increasingly dysfunctional as the numbers of student's increase, the numbers of applications for ethics review increase etc. It should be obvious that a dysfunctional REC would be very harmful for the institution.

- **Administrative systems for REC:**

- A confused administrative system has the potential to cause difficulties if information cannot be accessed quickly and accurately. Several aspects of the administrative system need special attention to achieve proper filing systems, to streamline processes, to enable appropriate follow-up (e.g. on non-receipt of progress reports) – **Online systems are encouraged**

A Study that Slipped Through – Why?

Le Grange, L. 2019. A comment on critiques of the article *Age and Education-related effects on cognitive functioning in colored South African women.* ***South African Journal of Higher Education*** http://dx.doi.org/10.20853/33-4-3715
Volume 33 | Number 4 | 2019 | pages 9–19

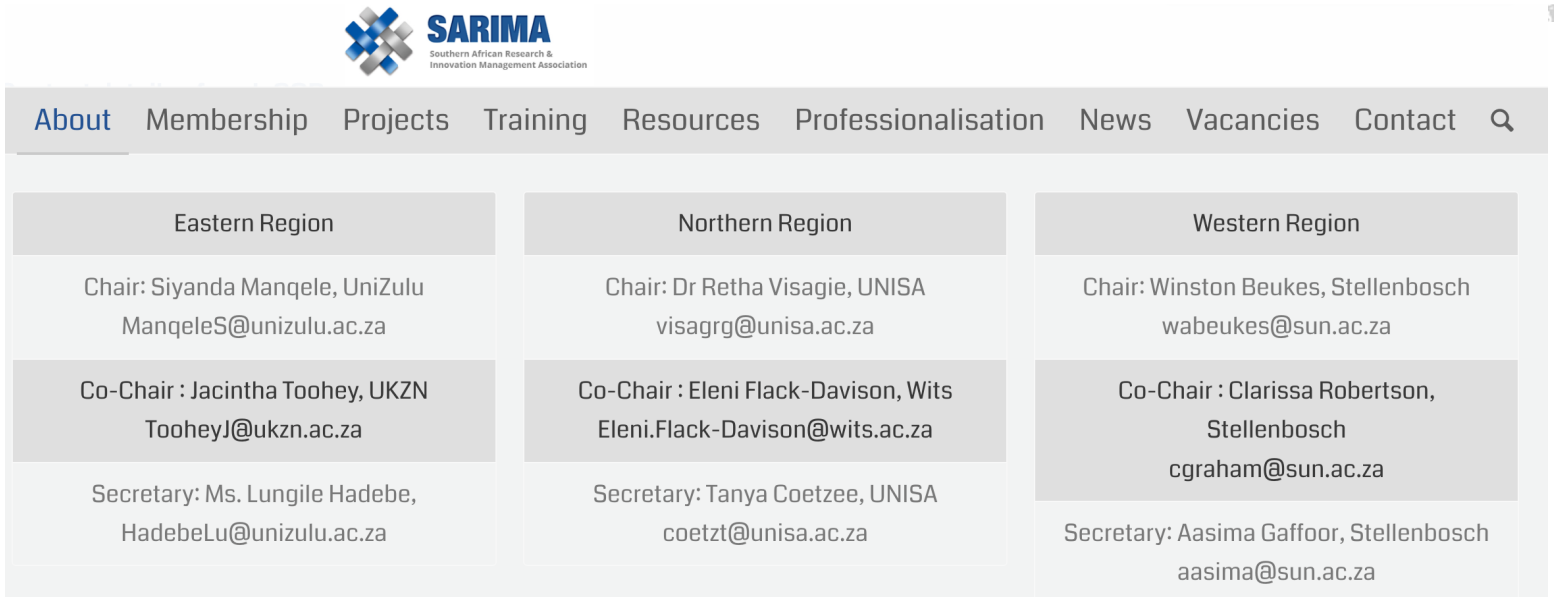
“Age and Education-related effects on cognitive functioning in colored South African women”.

The Study

- Outcry when published
- *Journal of Ageing, Neurophysicology and Cognition*
- Nieuwoudt, Dickie, Coetsee, Engelbrecht and Terblanche (2019)
- “Colored women in South Africa have an increased risk for low cognitive functioning as they present with low education levels and unhealthy lifestyles”
- Department of Sport Science

Issues

- Race based science – racial essentialism
- Coloniality
- Modern Western Science
- Blindness / bias in ethical clearance



Community of Practices for Research Ethics & Integrity

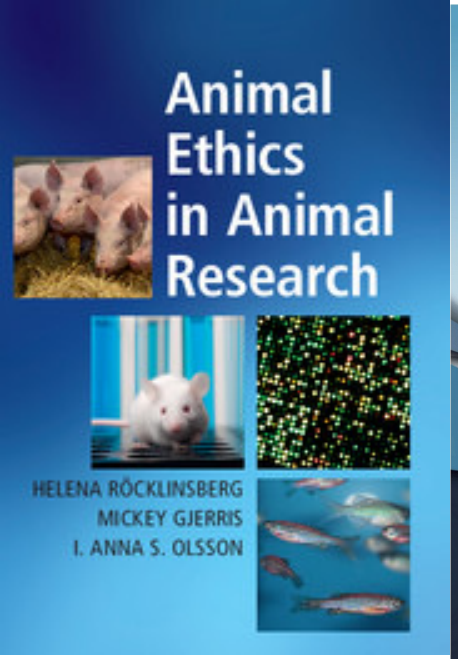
New Website

SARIMAhttps://www.sarima.co.za/resources/communities-of-practice-cop-s/

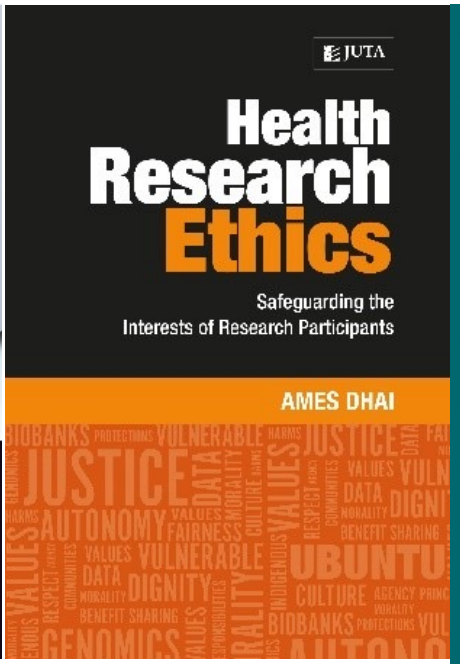
International Professional Recognition Council (IPRC)

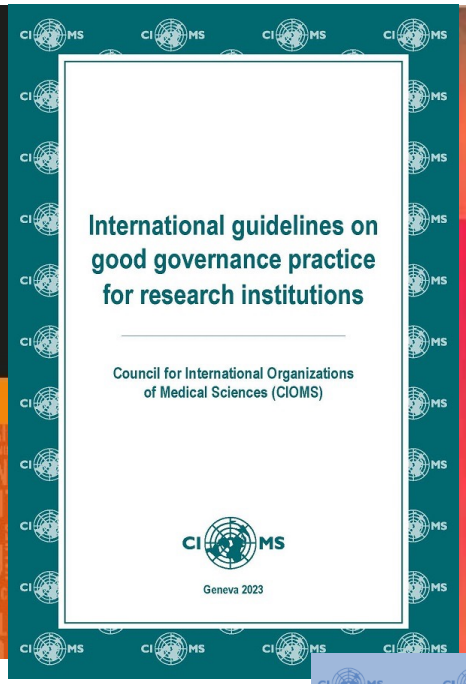
IPRC International Professional Recognition Council

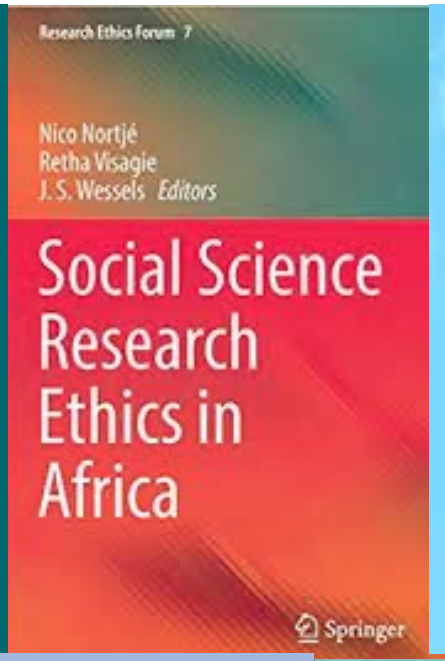
- Professional recognition is granted to research managers (including administrators) for their professional knowledge, based on prior learning, experience, functional and transferable expertise, regardless of whether such competencies were achieved formally.
- It constitutes an award or endowment which acknowledges the expertise and accomplishment of the research manager.
- Professional recognition is awarded through the review of a portfolio of evidence by peers on the IPRC.
- There are three options for the recognition of prior learning, expertise and experience: Research Administration Professional, Research Management Professional, and Senior Research Management Professional.


Animal Ethics in Animal Research
HELENA RÖCKLINSBERG
MICKEY GJERRIS
I. ANNA S. OLSSON


RESEARCH ETHICS IN AFRICA
A Resource for Research Ethics Committees
Mariana Kruger | Paul Ndebele | Lyn Horn

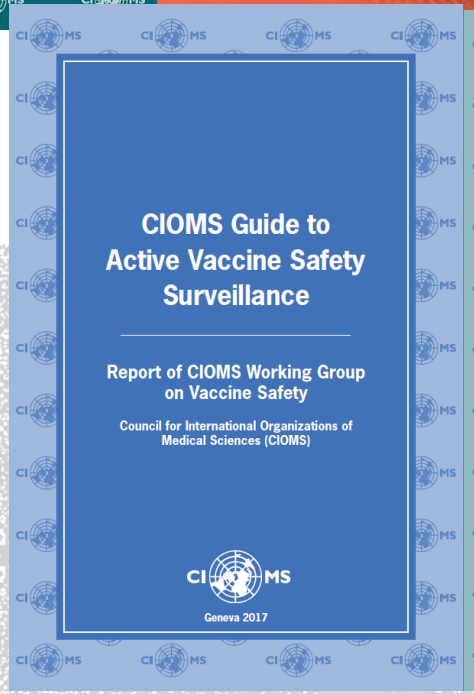

JUTA
Health Research Ethics
Safeguarding the Interests of Research Participants
AMES DHAI

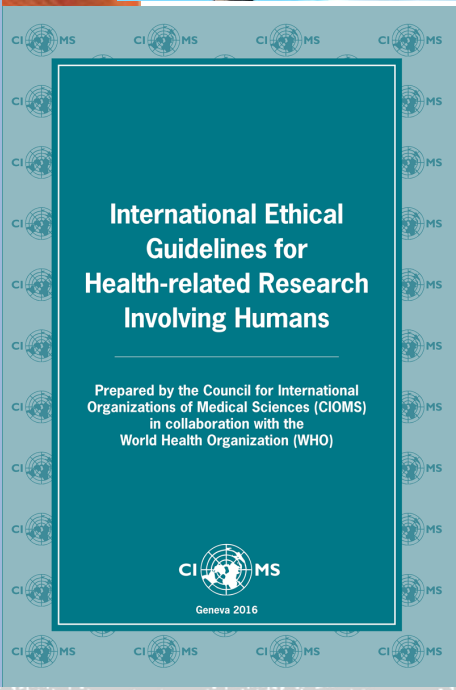

International guidelines on good governance practice for research institutions
Council for International Organizations of Medical Sciences (CIOMS)
CIOMS
Geneva 2023


Research Ethics Forum 7
Nico Nortjé
Retha Visagie
J. S. Wessels Editors
Social Science Research Ethics in Africa
Springer


ETHICS
RESPECT
HONESTY
INTEGRITY

Readings


CIOMS Guide to Active Vaccine Safety Surveillance
Report of CIOMS Working Group on Vaccine Safety
Council for International Organizations of Medical Sciences (CIOMS)
CIOMS
Geneva 2017


International Ethical Guidelines for Health-related Research Involving Humans
Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)
CIOMS
Geneva 2016

The end