




PRESENTATION: FACULTY OF THEOLOGY SEPT 2015

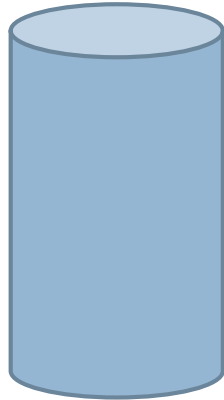
PROF MINRIE GREEFF

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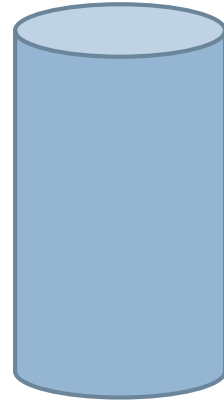
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- ❑ How important is high quality ethical research conduct to you as a Faculty of Theology?
 - ❑ How important is the rights and welfare of human participants?

The twin pillars of HUMAN protection in research

Rights and welfare of human subjects



Independent Review
(REC)



Written informed Consent

Presentation

- 1) Why the change?
- 2) What emergency actions did we take?
- 3) What do we have to do in future?
- 4) How serious is it?

1) Why the change?

- ▶ In 2003 the new National Health Act No 61 of 2003 was published
- ▶ Chapter 9 deals with Health Research and Information and emphatically states:

“Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted - in the prescribed manner; and with written consent ...”

- ▶ The establishment of a National Health Research Ethics Council (NHREC)
- ▶ Registered ethics committees
- ▶ The NWU decided to register one REC with the NHREC (somewhere between 2008 - 2011) to handle all research at the NWU through 10 research ethics sub-committees
- ▶ The registered committee met twice a year and the sub-committees each functioned according to their own rules

In 2012 all (33) registered Human Research Ethics Committees of the country were audited

Findings for NWU:

- ▶ *Major issues:*
 - ▶ Appointment of members
 - ▶ Records administration
 - ▶ Training
 - ▶ Standard Operating Procedures
- ▶ *Critical issues:*
 - ▶ Review process
 - ▶ Quorum

The letter to us on 10 June 2013 read:

“We alert you to the fact that your REC is not allowed to continue reviewing new research proposals until provision is made for a properly constituted REC that formally meets, reviews and approves new research proposals.

*Your REC is expected to adequately address the above audit findings to the satisfaction of the NHREC. Please provide us with your **corrective actions** within the specified period.”*
(12 months)

2) What emergency actions did we take?

- ▶ To apply for registration of three registered committees:
 - ▶ Health Research Ethics Committee (Potchefstroom campus)
 - ▶ Animal Ethics Committee (research with animals for the benefit of humans) (Potchefstroom Campus)
 - ▶ Animal Ethics Committee (research with animal for the benefit of animals) Mafikeng campus
- ▶ Restructuring the formerly registered committee to be a non-registered Institutional Research Ethics Regulatory Committee (IRERC) meeting twice a year with newly formulated rules (small task team in process of reformulating)

Follow up visits by the NHREC

- ▶ Early 2014 to see whether the corrective actions of the audit were addressed - *some changes were observed but concern was raised about some research still being done with humans not being approved by a registered REC.*
- ▶ By end November 2014 the newly registered HREC was visited by the NHREC and appreciation was voiced for the major changes made with this committee. *Once again great concern was voiced for research still being done at the NWU on human participants not approved by a registered HREC. We were informed that the AECs will soon be audited.*

Newly published Ethics in Health research: Principles, Processes and Structures (2015)

▶ Definition of Research

“Includes a range of activities conducted by many different disciplines that may use different methodologies and explanatory frameworks to extend knowledge through disciplined or systematic investigation” (p7 1.1.4 & p 79)

- ▶ The core ethical principles **apply to all forms of research that involve living human participants and use of animals** (also human biological material and data collected from living or deceased persons) (p7 1.1.7)
- ▶ NB These guidelines express the view that the core ethical principals apply to all forms of research that involves humans or use of animals (p8 1.1.12)
- ▶ The documents as *inclusive as possible*, so that **all researchers who involve human participants or use animals in their research** will find assistance in these guidelines (p8 1.1.13)
- ▶ NB In other words, although this document derives its authority from the NHA the NHREC intends it to address research more broadly to achieve the specific goal of providing guidance for researchers so that research involving **human participants or animals** may conduct research in accordance with the **highest ethical norms and standards** (p8 1.1.13)
- ▶ SA also attractive for **social, behavioral, political scientists, economists, researchers** engaged in *social development and education*, and many more disciplines (1.2.2)
- ▶ To ensure that SA's people are fairly and respectfully treated by researchers the research ethics systems and infrastructure are regularly upgraded and strengthened (1.2.3)

3) What do we have to do in future?

- ▶ IREC

- ▶ Reviewing the rules - registered and non-registered REC
- ▶ Risk level descriptors - all medium risk research through a registered REC

- ▶ Task group on the Potchefstroom campus

- ▶ Past year a task team under the leadership of Prof Fika has worked on solving the problem on the Potchefstroom campus.
- ▶ A document was developed outlining the process that ethics applications should follow - proposal committee and ethics committee
- ▶ In process of registering one additional ethics committee to accommodate research with human participants (health and health-related will go through the HREC; others through the proposed registered committee if more than minimal risk)
- ▶ To ensure that deans accept the responsibility to establish the necessary proposal committees within each Faculty/research entity utilizing the guidelines set out by the task team

4) How serious is it?

- ▶ NHREC can stop any ongoing and future research in health and health related research with human participants
- ▶ NHREC can investigate any research with humans possibly not adhering to the SA ethics framework
- ▶ This can jeopardies all research with human participants at the NWU
- ▶ Internal disciplinary actions (Category A and B violation)
- ▶ NHREC can refer matters concerning violations of ethical or professional rules to the relevant health professional council