

Health Research Ethics

Wits/Aberdeen University 2-day training
Mpumalanga Health Research Committee
Mpumalanga Department of Health

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Module I Health research and ethical principles



UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG



health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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What does this training cover?

Module I: Health research, ethical principles

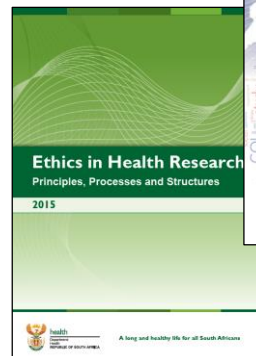
Module II: Norms, standards, and criteria

Module III: Research governance and RECs

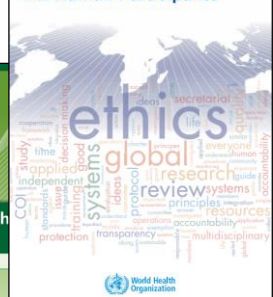
Module IV: Contemporary issues

Module V: Monitoring research conduct

Not specifically covered: Biological materials/Human tissue; Clinical/medical ethics, therapeutics; Genetics/genomics research but principles apply



Standards and Operational
Guidance for Ethics Review
of Health-Related Research
with Human Participants



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Introductions

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Module I

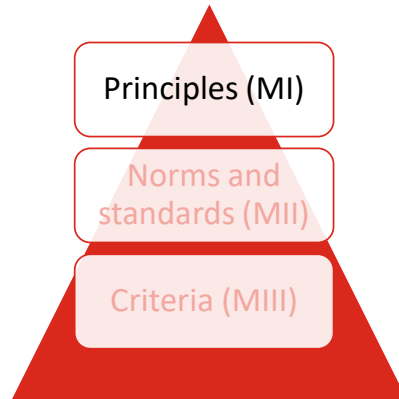
Introduction to health research and
ethical principles

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Module I Learning Outcomes

- a. Describe basics of study design in health research
- b. Identify and connect ethical principles in health research
- c. Appreciate decolonising global health research. Outline principle of solidarity

Group exercise: Apply ethical principles to research studies



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1a | What is health research? Basics of methodology & design

Systematic collection and analysis of new information undertaken with the goal of producing generalisable knowledge or improved understanding of the human condition in its environment or context

...may be understood to include but is not limited to research that contributes to knowledge of

- biological, clinical, psychological, or social welfare matters including processes as regards humans
- the causes and effects of and responses to disease
- effects of the environment on humans
- methods to improve health care service delivery
- new pharmaceuticals, medicines, interventions and devices
- new technologies to improve health and health care

Source: [NDoH, 2015](#)

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What is health research? (2)



Research involving human participants - any social science, biomedical, behavioral, or epidemiological activity that entails **systematic collection or analysis of data with the intent to generate new knowledge**;

in which human beings:

- (i) are exposed to manipulation, intervention, observation, or other **interaction with investigators** either directly or through alteration of their environment, or
- (ii) become **individually identifiable** through investigators' collection, preparation, or use of biological material or medical or other records.

Source: [WHO Research Ethics Review Committee \(ERC\)](#)

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What is health research? (3)



- In general terms, research includes a wide range of activities conducted by **many different disciplines that may use different methodologies and explanatory frameworks**
- In the physical and biological sciences, research may be described as a systematic study or inquiry, usually using quantitative data, in seeking generalisable new knowledge
- Health-related research is increasingly also using qualitative methodologies. The humanities, social and behavioural sciences use both qualitative and quantitative methods and analytic frameworks, all of which may be aimed at contributing to **knowledge about the human condition in its environment and context**

Source: [NDoH, 2015](#)

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There is a need to demystify science...

- Einstein said, “The whole of science is nothing more than refinement of **everyday thinking**.” Most of us may be conducting some research in our daily life.
E.g.: When we want to buy a car we collect information about models and dealers, analyse, then try to reach “scientific” conclusion on which car to buy
- Use of **complex instrumentation not necessary** for good research. Key attributes of good research are proper planning, accuracy in data collection and proper unbiased interpretation
- **Moral conduct** in interactions with participant and researchers, and with identifiable information on research participants



Source: [WHO, 2004](#)

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Types of research studies Health research, what it is not?

RECs may review different types of research studies, including, but not limited to:

- clinical trials
- epidemiological research
- social science research
- research on medical records or other personal information
- research on stored samples
- health systems research
- implementation research

Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews usually do not constitute research and thus usually do not undergo formal ethics review.

Sources: [WHO, 2011](#); [NDoH, 2015](#)

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Quantitative health research

- Process of collecting and analysing numerical data
- Purpose is to measure the magnitude of an event, to make predictions, develop causal explanations
- **Deductive** approach where emphasis is placed on the testing of theory, or hypothesis, shaped by empiricist and positivist philosophies

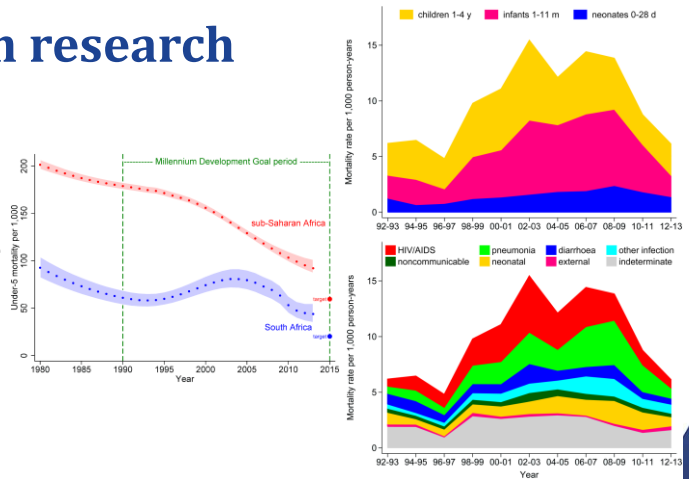


Fig 1. Under-five mortality estimates (with 90% uncertainty bounds) from UNICEF for sub-Saharan Africa and South Africa from 1980 to 2013, together with respective MDG4 target levels for 2015 (two-thirds reduction from 1990)

Fig 2. Under-five mortality rates at the Agincourt site from 1992 to 2013, by age group and by cause of death category

Source: [Byass et al, 2015](#)

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Qualitative health research

- Human condition in context ([NDOH, 2015](#))
- Collection and analysis of non-quantitative data about peoples' experiences of health, illness and healthcare ([Rolfe et al 2018](#))
- Non-probability sampling
- **Inductive** in nature, richness and depth, determining meaning through description of experiences and views ([Al-Busaidi, 2008](#))

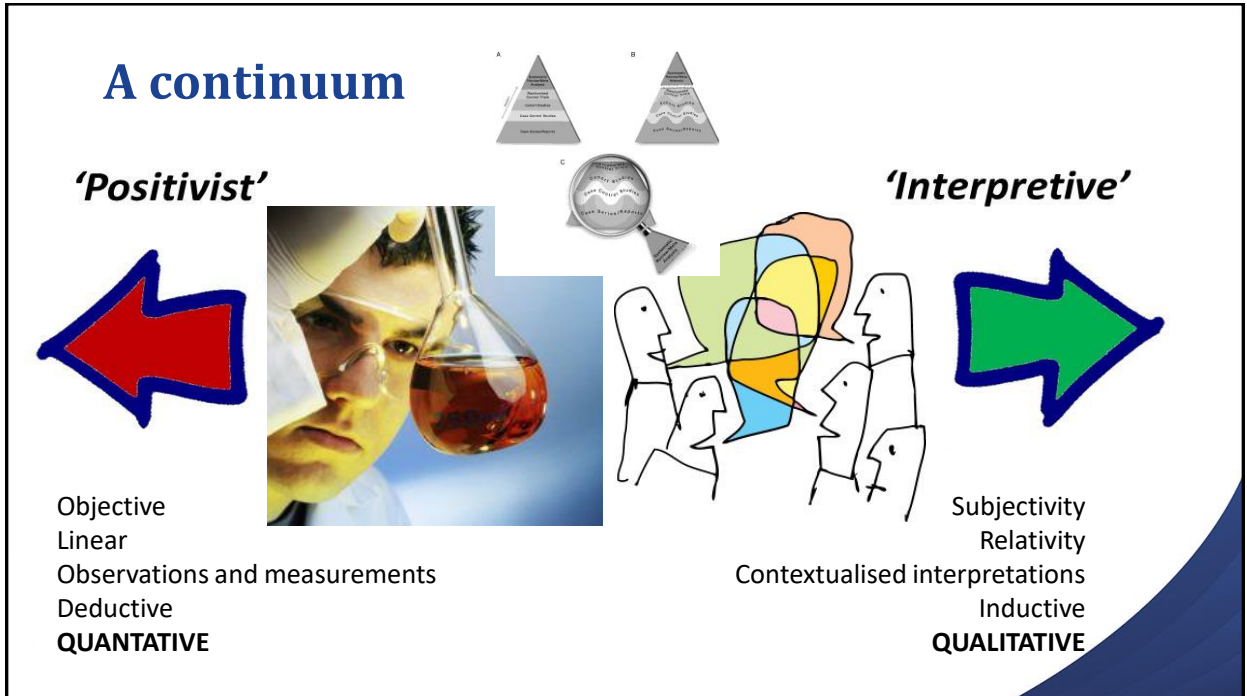
*"...Some, when they realize that his CD4 count is getting better, and he realize that they are going to take away the grant and he will struggle ... he stops taking his treatment and he will remain sick."
[Village Official]*



Fig 1: Focus group discussion (FGD) participant showing hand gestures used by medical staff to disclose HIV/AIDS status. Permissions were secured from participants for the reproduction of this image.

Source: [Hullur et al, 2016](#)

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Secondary research

Research that relies exclusively on publicly available information or accessible through legislation or regulation usually need not undergo formal ethics review... provided that

- the researcher does not interact directly with individuals or groups
- the researcher does not stage any intervention
- the individuals or groups do not have a reasonable expectation of privacy
- dissemination of research findings does not identify individuals or groups

Source: [NDoH, 2015](#)

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1b | Ethical principles

Universal, standards, references, abstract, cross-culturally valid but flexible

1. Autonomy
2. Beneficence
3. Non-maleficence
4. Justice



'No segment of the population should be unduly burdened by the harms of research or denied the benefits of knowledge derived from it.'

Beauchamp TL, Childress JF (2001) Principles of Biomedical Ethics (fifth edition). New York: Oxford University Press.

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Autonomy (respect for persons)

The right for an individual to make his or her own choices

- The right not to be injured or mistreated
 - The right to give informed, un-coerced consent to participate in research
 - The right to privacy, confidentiality and/or anonymity
- **Informed consent:** Respect for the individual's right to make decisions about themselves and their life (respect for autonomy) requires that research participants are adequately and properly informed regarding the nature of the research project.

"it is not acceptable that the welfare and the respect of the individuals be compromised in the pursuit of benefits that may accrue to science and society"

[WHO, 2004](#)

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Justice (equality)

Fairness and equality among individuals

- Distribution of capabilities and resources to ensure “least advantaged” benefitted and not harmed or forgotten
- All patient groups, including vulnerable, have right to participate in, indeed may be necessary participants in, investigations to improve health care and to evidence for care
- **Choice of study population**, recruitment, post-study benefits, Who should participate? Should certain groups be excluded on grounds of vulnerability?

If such [medical] research is successful, distributive justice demands a fair and equitable distribution of its benefits to all who contributed in making it possible....

Ethics review committees in Africa seem to be as yet insufficiently aware of the implications of distributive justice or else they would not be approving so many studies with-out any guarantees that distributive justice would be applied in the event of successful results

[Tangwa, 2009](#)

Source: White, 2017

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Beneficence and non-maleficence

Acting in best interests of other, “above all, do no harm”

- Beneficence (do good)
- Non-maleficence (do no harm)
- Ethical obligation of maximising benefit while minimising harm especially for research subjects
- **Risk of harm** must be reasonable in light of anticipated benefits: ensure research aims at achieving some good, that expected benefits outweigh any foreseeable risks, and that in carrying it out human subjects not harmed

“In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests”

[Article 6 of the Declaration of Helsinki World Medical Association 2008](#)

Source: White, 2017

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International instruments

- [Nuremberg Code \(1947\)](#)
- [United Nations Declaration on Human Rights \(1948\)](#)
- [United Nations Convention on the Rights of the Child \(1989\)](#)
- [Belmont Report \(1979\)](#)
- [Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects \(WMA 2008\)](#)

RECs should use principles... articulated in international human rights and research ethics guidance documents as the basis for evaluating research proposals... RECs should make clear which specific ethical guidelines are relied on in making their decisions; the guidelines should be readily accessible to researchers and other interested persons, including general public [NDoH, 2015](#)

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1c | Decolonising health research

*“The principles, in the terms, language and idioms ... are, of course, very much a **paradigm of the western industrialized world**, where their relevance and urgent applicability have been made abundantly manifest by various activities that violated or that run the risk of violating them”*

[Tangwa, 2009](#)

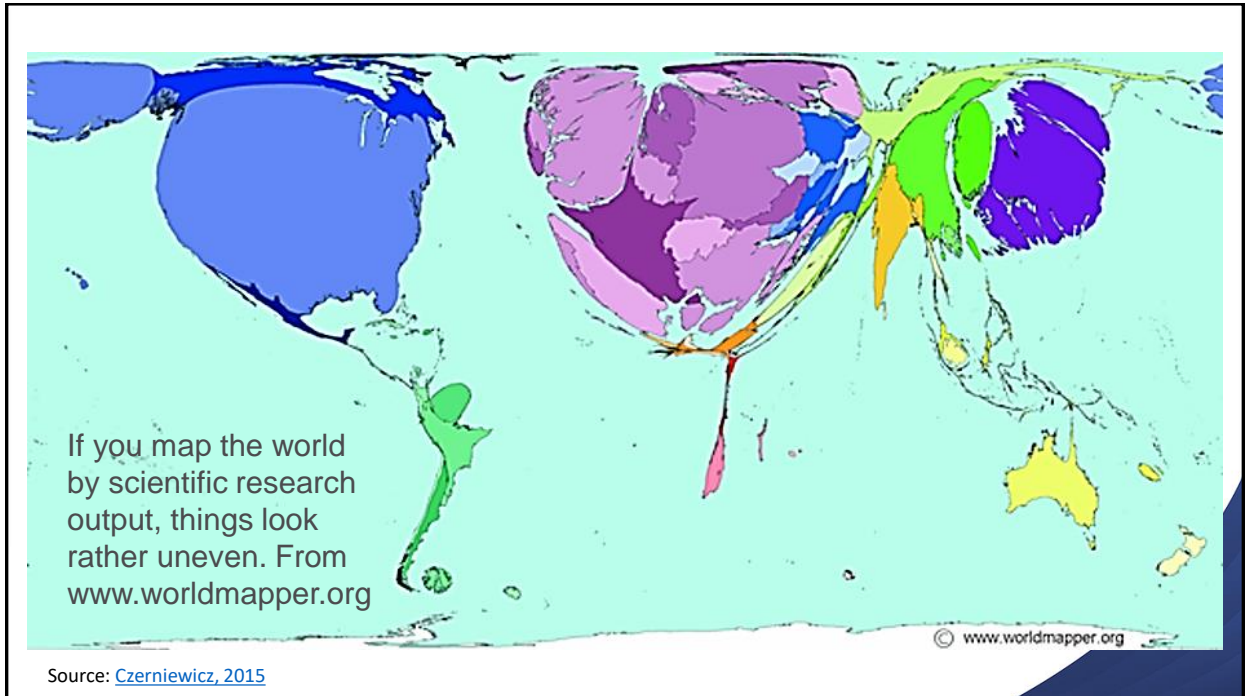
...health research in Africa has been predominantly externally funded and this presents both opportunities and challenges.

Opportunities are in the form of skills and technology transfer, research infrastructure development, and sharing of resources.

Challenges, on the other hand, have been cited as failure to address priority evidence gaps, lack of local ownership, and exploitative research partnerships, focusing on publications as opposed to capacity-building

[Nabyonga-Orem, 2021](#)

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Decolonising research

Arguably, one of the greatest achievements of European colonization of Africa was to establish Europe—and the European—as the standard to which Africans must conform to be considered as civilized or ‘developed’.


This meant delegitimizing and silencing indigenous populations as generators and possessors of knowledge, thus creating a cognitive empire that extends to and goes beyond the realms of health and healthcare.

[Atuire & Olivia U Rutazibwa, 2021](#)

Vaccine inequity and injustice is not just a moral failure. It is also a health and economic catastrophe [WHO 2022](#)



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WEBINAR Justice advancement through decolonisation: Chipping away at structures and processes

hsg
Health Systems
Global

..Aboriginal health research ethics gives much greater prominence to ethical principles that assist in decolonising research practice such as “self-determination”, “community-control”, and “community ownership”. [Harper and Pratt 2021](#)

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The principle of solidarity

- “solidarity brought people together in **resistance to government and in longing for social change.... citizens** could neither be ignored nor destroyed... standing together, especially where people are threatened, supporting each others’ interests, and having **shared aims.**” [Dawson and Verweij, 2012: p1](#)
- “**shared purpose**, as in cases ...amongst striking workers...**mutual support**’ [Davies and Savulescu, 2019: p133; 134](#)
- “Solidarity is the **indispensable tool of the oppressed** ... it may explain why some societies ‘flatten the curve’ of an infectious disease outbreak, while others, despite advanced health sectors and high GDP, are ineffective or unable to **maintain public support** for emergency measures” [Kolars, 2021: p122](#)

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Decolonising global health research

“A critical element of **solidarity** is its characterisation as ‘we-thinking’. This distinguishes it importantly from charity, which is purely other-directed. In a solidarity-based arrangement people not only give to others, but are entitled to expect something back.”

Davies and Savulescu, 2019: p134



Trust, Solidarity and COVID-19
Hecht-Levi Fellow Rachel

Definition and importance of solidarity

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1d | Relate ethical principles to different case examples (group exercise, 1 hour)

3 groups provided with an outline of a research study (abstract from a peer reviewed research article)

In group discussion, each group takes 15-20 mins to read, discuss and appraise:

- a) What type of health research is this?
- b) What ethical principles could be relevant ?
- c) Prepare to feedback an assessment of the study, in terms of the type of health research and applicable ethical principles, in plenary

Each group feeds back assessment in plenary 5 mins presentation, plus Q&A

Appoint a) chairperson and b) rapporteur and work through abstract using materials from Module 1

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Group exercise: Apply ethical principles to research studies

