Health Research Ethics

Wits/Aberdeen University 2-day Training

Mpumalanga Health Research Committee
Mpumalanga Department of Health

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August 2022

Module II
Norms, standards and criteria

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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

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Module II

Norms, standards and criteria for ethical review and evaluation

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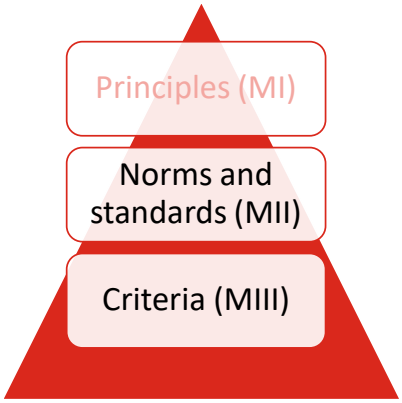
Module II Learning Outcomes

a) Describe ethical norms and standards

b) Orient to and apply criteria for ethical review and evaluation

c) Appreciate vulnerability and relate to decolonising research debates

Group exercise: Perform ethical review



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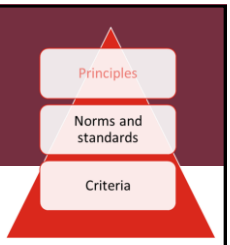
2a | Norms and standards



1. **Relevance and value**: responsive to needs of the people of South Africa
2. **Role-player engagement:** assuring acceptability through engagement with various stakeholders throughout process
3. **Researcher competence and expertise:** suitable qualification technical competency
4. **Scientific integrity**: robust design and methodology
5. **Fair selection of participants:** inclusion/non-discrimination
6. **Informed consent:** voluntariness and informed choices are evidenced
7. **Ongoing respect for participants:** including privacy and confidentiality
8. **Fair balance of risks and benefits**: balancing risk and benefit

Source: NDoH, 2015

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1: Relevance and value
2: Role-player engagement

Relevance and value

Research relevant/responsive to needs of people of South Africa

Proposals should explain anticipated contribution to knowledge generation

Ideally, how findings might be translated into products, interventions, processes or services to improve well being of South Africans

Role player engagement

Engage key role players at various stages of planning and conducting research to improve quality and rigour, to increase acceptability to key role players, to harness role player expertise, and offset power differentials

Engagement may comprise various activities, including awareness-raising initiatives for role players, including but not limited to participating communities

Sources: WHO Research Ethics Review Committee (ERC); NDoH, 2015

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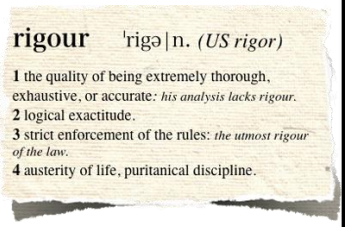
3: Researcher competence, expertise
4: Scientific integrity



- Qualifications/ Competence/ Technical expertise
  - Publications
  - Letters of support
  - Research ethics training
- South African investigators (international research)
- Dissemination, positive or negative, in timely accessible way including to communities
- Design and methodology rigorous
- Validity: credibility of findings to those studied
- Generalisability: translation (not transplantation) of findings to other settings and groups
- Reliability: extent to which same methods will yield the same results

Sources: WHO Research Ethics Review Committee (ERC); NDoH, 2015

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5: Fair selection of participants
6: Informed consent
7: Ongoing respect for participants

- Selection of study populations/ participants
- Recruitment
- Inclusion criteria
- Exclusion criteria
- Avoiding discrimination
- Study information
- Verbal/written
- Time to absorb
- Time to ask questions
- Freedom to withdraw
- Informed consent processes
- Privacy: Access to personal information
- Confidentiality: preventing disclosure of identifiable information
- Anonymity: protecting identities
- Data management plans: data storage, retrieval, access, sharing, gatekeeping

Sources: WHO Research Ethics Review Committee (ERC); NDoH, 2015

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8: Balancing risks and benefits

The table below lists examples of the potential risks/harms and benefits that may accrue to research participants as a result of taking part in research.

Risks/Harms	***Benefits***
Physical harm	*Access to treatment/ Free treatment*
Social harm/social risk	*Emotional support*
Emotional harm/risk	*Psycho-social support*
Stigmatisation	*Humanitarian*
Loss of privacy	*Contribution to society*
Insensitivity to vulnerabilities, exposing individuals to various types of harms/risks	*Others*
Sharing of confidential information resulting in tangible or intangible losses	
Perpetuation of gender and other biases	
Others	

Sources: WHO Research Ethics Review Committee (ERC); NDoH, 2015

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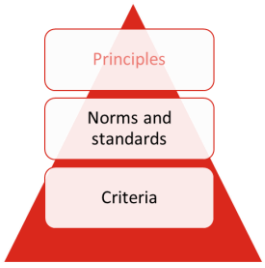
2b | Criteria for ethical review and evaluation

1. Scientific design, aims & objectives
2. Inclusion & exclusion criteria
3. Selection of study population & sampling
4. Recruitment & enrolment
5. Research procedures
6. Risks of harm & likelihood of benefit
7. Reimbursements, inducements & costs for participants
8. Participants' privacy & confidentiality interests
9. Obtaining informed consent



Sources: WHO Research Ethics Review Committee (ERC); NDoH, 2015

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1. Scientific design, aims & objectives

- Methodology must be reviewed, using appropriate disciplinary standards
- Suitability of methods should be explicitly justified (methodology)
- Sound methods must be evidenced by prior scientific review
- Research must be worthwhile
- Stated aims and objectives achievable and provide valid outcomes
- Ethical implications of methodology must be considered
- Disciplinary variations wrt. scholarly review

Sources: WHO, 2011; NDoH, 2015

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2. Selection of study population & sampling
3. Inclusion and exclusion criteria

- Distributive justice (equality) key principle
- Sharing of the burden of research, equality of participation
- Benefits for study populations should be assessed
- Timeliness of benefits for study populations should be assessed
- Risk/benefit analysis: are risks to participants offset by anticipated benefits
- Participants selection appropriate for research question
- Rationale for number of participants and connection to aims and objectives
- Power calculation
- Inclusion of vulnerable participants requires justification

Sources: WHO, 2011; NDoH, 2015

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4. Recruitment and enrolment

- Neutral recruitment strategies, with information on purpose of research, risks and benefits
- Full description of recruitment methods, avoidance of selection bias
- Location, timing and context of recruitment and enrolment
- Protection of privacy and confidentiality
- Managing therapeutic misconception
- Assessing excessive burden or risk exposure

Sources: WHO, 2011; NDoH, 2015

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5. Research procedures

- Clear in rationale, clear in detail
- Feedback of results of participants should be made clear
- Researchers should have competence/expertise commensurate with research procedures
- Research procedures should not disrupt routine treatment and management of patients of functioning of facilities

Sources: WHO, 2011; NDoH, 2015

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6. Risk of harm and likelihood of benefit

- Risks of harm should be outweighed by anticipated benefits to those involved, community, health systems and society at large
- Risk/benefit ratio: elements to consider:
  - harms and benefits adequately identified, evaluated and described;
  - harms in proposal match those in informed consent documentation;
  - risk of harm reasonable relative to anticipated benefit;
  - risk of harm reasonable relative to importance of anticipated knowledge gained;
  - counselling and support services be made available if appropriate
- Remedial actions should harms occur
- Harms may include physical, psychological, legal, social and financial
- Harms of researchers/data collectors

Sources: WHO, 2011; NDoH, 2015

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7. Reimbursements and inducements

- There should be no costs to pax. to be involved in research
- Reimbursement of costs for travel, refreshments, and inconvenience
- Reimbursement for time (time has value that could be otherwise spent)
- Fair reimbursement: Time, Inconvenience and Expenses (TIE) method
- Pro rata reimbursement if pax withdraw from study
- Parental reimbursement for research with children
- Inducement and assessment of risk of harm by participants
- Community members input may be useful in explanation and justification

Sources: WHO, 2011; NDoH, 2015

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8. Participants' privacy and confidentiality

- Privacy – person's interest in controlling access to personal information
- Confidentiality – whether and how research data might be disclosed
- Data management: how data will be secured, retained, stored, shared
- Procedures for notifiable information e.g. criminal activity, notifiable disease
- Confidentiality and focus groups
- Protection of Personal Information Act 4 of 2013: person should know what information being collected, why, what will happen to it, how long it will be retained, whether it will identify the person, whether it will be shared and why, whether it will be sent outside South Africa and why. Person should agree to these terms

Sources: WHO, 2011; NDoH, 2015

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9. Informed consent

informed consent necessary but insufficient element of ethical research, i.e. that person voluntarily chooses to participate does not mean that research is ethical

- Persons must choose voluntarily about participation on basis of information
- Provision of information and engagement with person before decision: nature and quality should be assessed
- Sufficient time to consider information, consult others, ask questions, reach informed decision
- Quality of information, quality of process to facilitate understanding
- Plain language, translated appropriate to context
- Involvement, purpose, activities, risks/benefits, freedom to withdraw, reimbursement, confidentiality and privacy

Sources: WHO, 2011; NDoH, 2015

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Governance structures must be adaptive

Norms/standards	Criteria
1. Relevance and value	?
2. Role-player engagement	?
3. Researcher competence	1. Scientific design, aims and objectives
4. Scientific integrity	5. Research procedures
5. Fair selection of participants	2. Inclusion and exclusion criteria 3. Selection of study population and sampling 4. Recruitment and enrolment
6. Informed consent	9. Obtaining informed consent
7. Ongoing respect for participants	7. Reimbursements, inducements and costs 8. Privacy and confidentiality
8. Risk/benefit analysis	6. Risks and benefits

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Community considerations

- Acknowledging impacts on communities where research occurs and/or to whom findings can be linked
- Duties to respect and protect communities require examination to minimising any negative impact e.g. stigma, draining local capacity
- Promoting positive impacts including related to health impacts (health literacy, health behaviour) as well as on capacity development
- Researchers should actively engage with communities on design and conduct of research (including informed consent)
- Researchers should be sensitive to and respectful of local cultural, traditional and religious practices

Source: WHO, 2011

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"Researchers should be familiar with legislation and other binding instruments relevant to research" (selected examples)

- Child Justice Act 75 of 2008
- Children's Act 38 of 2005
- Choice on Termination of Pregnancy Act 92 of 1996
- Constitution of the Republic of South Africa, 1996
- Domestic Violence Act 116 of 1998
- Employment Equity Act 55 of 1998
- Protection of Personal Information Act 4 of 2013

Source: NDoH, 2015

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The principle of solidarity

- "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: p133; 134
- "**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" Kolers, 2021: p122

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2c | Vulnerability

Diminished ability to fully safeguard one's own interests; limited capacity /access to social goods like rights, opportunities and power

1. Context: Incidents/emergencies
2. Children, adolescents, orphans
3. Women (pregnant women and foetuses)
4. Adults with limited capacity or incapacity
5. Physical disability, dependency, in treatment
6. Prisoners
7. Collectives

Source: Kruger, Ndebele and Norn, 2014; NDoH, 2015

A vulnerable research participant is someone who, because of some characteristic or prevailing set of circumstances, is at risk of being exploited or harmed in the course of biomedical research. Research ethics committees (RECs) must take special care when approving research involving vulnerable research participants or communities
Khorn, Sleem, Ndebele 2014

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Vulnerability and ethical principles

Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

Medical research involving a disadvantaged or vulnerable population or community is **only justified** if the research is **responsive to the health needs and priorities of this population or community** and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

Declaration of Helsinki WMA 2008

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Vulnerability in context

- Refugees
- AIDS orphans
- Characteristics or behaviour that could lead to stigmatisation, include albinism, infertility, the practice of homosexuality and the practice of 'witchcraft' or divination
- Stigmatised groups, include groups consisting of commercial sex workers and substance abusers
- Illiteracy and language barriers
- Poverty

Source: Kruger, Ndebele and Norn, 2014

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Vulnerability: REC considerations

- **Community engagement**: essential that research with vulnerable groups is sensitive to their needs, where appropriate, researchers should actively engage, on an on-going basis, with representatives of the group/community concerned
- **Informed consent**: risk of consent not truly informed or voluntary is a critical issue in this context. RECs may consider independent assessment/ monitoring
- **Active monitoring**: with vulnerable communities should be attempted in some form (acknowledging implications for both human and financial resources)
- **Risk/benefit analysis**: REC plays gatekeeper role and has the ability to protect vulnerable comminates, acknowledging need to avoid paternalism
- **Vulnerability extends to institutions and countries**: in the context of international research it is possible for institutions and countries to be exploited

Source: Kruger, Ndebele and Norn, 2014

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RECs and Community engagement

- Has the study clearly defined both the research and the broader community, are proposed engagement mechanisms appropriate?
- What should the direct benefits of the research be for the community involved?
- Does the research question answer a community priority?
- How will the findings be translated into action to address the identified priority area?
- How will possible individual and community harm be minimised?
- Will the research conduct stakeholder analysis, are there independent sources from which relevant information can be obtained?
- Will the research establish a CAB, or is there a CAB already present in the area? If one still needs to be established, what process has to be undergone for establishing the CAB, and will the anticipated process be both inclusive and democratic?
- How will study explore power dynamics among different community stakeholders to ensure true representation of community?
- Are the responsibilities of researchers towards the participants, the wider community and the CAB clearly defined?
- How will community consultation and partnership building be sustained throughout the research project's life cycle?
- Will researchers concerned be guided by a communications plan in the process and the end-of-study results dissemination?
- Has the committee taken note of project documents related to community engagement that have yet to be developed in full and presented to the committee for ethical approval? (Such documents could include: the communications plan; the community engagement plan; the related standard operating procedures (SOPs); and the information, education and communications (IEC) materials pertaining to the study.
- Will the research project recruit staff from local or central government health institutions, and, if so, will this compromise or weaken the community health system involved?

Source: Kruger, Ndebele and Norn, 2014

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2d | Perform ethical review (group exercise 1.5 hour)

3 groups provided with fuller details of research study (full text of peer reviewed research protocol)

In semi-structured discussion, each group takes 45 mins to read, discuss and appraise:

a) Identify and relate ethical principles, referring to norms, standards and criteria? Gaps?

b) Assess vulnerability aspects, decolonisation

c) Balance risks and benefits, outline feedback

Each group feeds back their assessment in plenary with a 5 mins presentation and Q&A

Appoint a) chairperson and b) rapporteur and work through abstract using materials from Module 2

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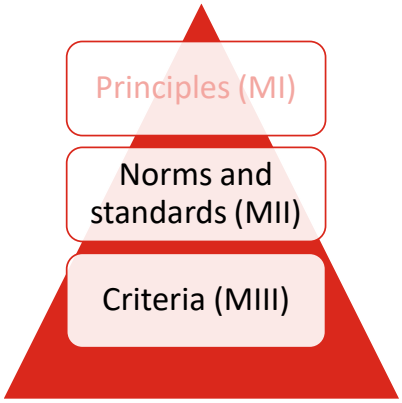
Module II Learning Outcomes

a) Describe ethical norms and standards

b) Orient to and apply criteria for ethical review and evaluation

c) Appreciate vulnerability and relate to decolonising research debates

Group exercise: Perform ethical review



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