Health Research Ethics

Wits/Aberdeen University 2-day Training

Mpumalanga Health Research Committee, Mpumalanga Department of Health

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Module V
Monitoring research conduct

UNIVERSITY OF ABERDEEN · UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG · vapar · AGINCOURT 30 YEARS · health MPUMALANGA PROVINCE REPUBLIC OF SOUTH AFRICA

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What does this training cover?

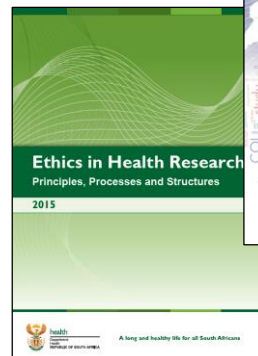Module 1: Health research, ethical principles

Module 2: Norms, standards, and criteria
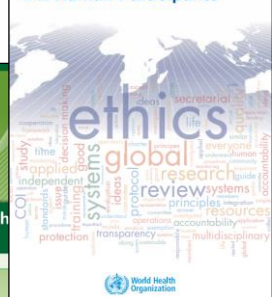
Module 3: Research governance and RECs

Module 4: Contemporary issues

Module 5: 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

ethics

World Health Organization

Ethics in Health Research
Principles, Processes and Structures
2015

health Department REPUBLIC OF SOUTH AFRICA

A long and healthy life for all South Africans

vapar

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Module V

Monitoring research conduct

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Module V Learning Outcomes

a) Describe safeguarding

b) Discuss research misconduct and whistleblowing

c) Outline Conflicts of Interest (COI)

d) Recognize publication ethics and intellectual property (IP)

e) Locate outputs and impact

Group exercise: reflections and feedback

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5a | Safeguarding

"Increasingly urgent focus on concepts of vulnerability, risk, harm and power relations for those participating in both national and global health research"

The nature of research presents specific situations in which abuses of power may occur and requires a tailored framework and approach"

NIHR | National Institute for Health and Care Research

Source: NIHR Safeguarding Guidance

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Definitions

"…a culture in which harm and abuse is less likely… "

"preventing and addressing any sexual exploitation, abuse, or harassment of research participants, communities and research staff, plus any broader forms of violence, exploitation and abuse ... such as bullying psychological abuse and physical violence". (UKCDR, February 2020)

UK's donor commitments to safeguarding, members of the UK Collaborative for Development Research (UKCDR), including DHSC, DFID, BEIS, UKRI and Wellcome Trust, signed an International Development Research Funders Safeguarding Statement to develop and maintain the highest standards in organizational culture, systems and practice required to prevent and address all incidents of harm and abuse

Source: NIHR Safeguarding Guidance

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NIHR | National Institute for Health and Care Research

Boundaries

- Includes not engaging in sexual activity with any individual under the age of 18, even if the age of majority/consent lower in relevant territory. Includes children and vulnerable adults in the community who are not direct beneficiaries but may be vulnerable to abuse and harm

- In addition, organizations should take all reasonable steps to prevent actual, attempted or threatened sexual exploitation, abuse or harassment, transactional sex or any other form of violence, exploitation and abuse such as bullying, psychological abuse and physical violence

- Appropriate vetting and checks, when engaging staff, consultants, sub-contractors and suppliers

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Resources

UKCDR Guidance on Safeguarding in International Development Research

DFID Enhanced Due Diligence: Safeguarding for external partners

DAC Recommendation on Ending Sexual Exploitation, Abuse, and Harassment in Development Co-operation and Humanitarian Assistance

Safeguarding policy templates (BOND)

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Training and support

Safeguarding Resource and Support Hub

BOND learning resources:
- Good safeguarding practice
- Managing safeguarding investigations
- Safeguarding governance for boards of trustees

Eight principles for building trust through feedback

Prevention of Sexual Exploitation and Abuse. UN Personnel Funds and Programmes.

Safeguarding children and child protection. NSPCC Learning.

Safeguarding. NCVO Knowhow.

Introduction to Safeguarding in the International Aid Sector. Online course

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5b | Research misconduct and whistleblowing

A whistleblower discloses information he or she reasonably believes evidences:

- a violation of a law, rule, or regulation

- gross mismanagement, gross waste of funds, or abuse of authority

- a substantial and specific danger to public health or public safety (US Office of Special Counsel, 2010)

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Research misconduct and whistleblowing

Consequences of not reporting misconduct 'has the potential to weaken the self-regulation of science, shake public confidence in the integrity of science, and forfeit the potential benefits of research…. scientific community, society, and the personal integrity of individuals all emerge stronger from efforts to uphold the fundamental values on which science is based'

- Mandatory reporting: demanding and self-destructive for the researcher

- Alternatives to reporting? Considering the nature of the misconduct?

- Institutions have a duty to make reporting safe and efficient, failure to ensure safety of whistleblowers limit the duties potential whistleblowers have

  - **As a minimum standard: have policies in place**

Source: Vie, 2020

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5b | Publication ethics and Intellectual property (IP)

…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

Nabyonga-Orem *et al. Health Res Policy Sys* (2021) 19:11
https://doi.org/10.1186/s12961-020-00676-9

Health Research Policy and Systems

RESEARCH   Open Access

The state of health research governance in Africa: what do we know and how can we improve?

Juliet Nabyonga-Orem[1*], James Avoka Asamani[1] and Micheal Makanga[2]

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Publishing ethics

…standards of expected ethical behaviour by all parties involved in the act of publishing:
- author
- journal editor
- peer reviewer
- publisher
- society for society-owned or sponsored journals

…includes all parties treating each other with respect and dignity and without discrimination, harassment, bullying or retaliation

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Duties of authors

- Reporting standards

- Data access and retention

- Originality and acknowledgement of sources

- Multiple, redundant or concurrent publication

- Confidentiality

Authorship of the Paper

Hazards and Human or Animal Subjects

Declaration of Competing Interests

Notification of Fundamental Errors

Image Integrity

Clinical Trial Transparency

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Intellectual property (IP)

Ethical issues regarding intellectual property arise concerning how group member's contributions should be measured and rewarded if the research project results in a patent, how businesses, advisors, and other institutions may have a claim to intellectual property resulting from projects they sponsor, and intellectual property and confidentiality agreements companies may ask students to sign to protect the intellectual property rights of a company.

- Patents

- Copyrights

- Trademarks

- Trade secrets

Source: Illinois Library, 2022

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IP, continued

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Open Data Commons License - http://opendatacommons.org/licenses/

Databases, can be copyrighted or licensed. It is important to understand data licensing from the perspective of both the data user and data creator.

Data Users: Re-use of existing data must clarify ownership, obtain permissions if needed, and understand limits set by licenses. Appropriate attribution and citation.

Data Creators: Applying appropriate licensing when data are released will help ensure proper re-use and attribution. There are many licenses available that represent the range of rights for the creator and licensee of the data. Two options for providing open licenses for research data are:

Source: Princeton University Library, 2022

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5c | Conflicts of interest (COI)

- Circumstances in which professional judgments or actions regarding a primary interest, such as the responsibilities of a medical researcher, may be at risk of being unduly influenced by a secondary interest, such as financial gain or career advancement.

- Secondary interests may be financial or non-financial, and the resultant bias may be conscious or unconscious

- COIs can incline/bias researchers towards secondary interests. Potential to undermine research

- COI core concept in research integrity

Source: Romain, 2015; Embassy of Good Science, 2022

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Conflicts of interest

Conflicts between personal interests and the interests of the researchers.

In the context of peer review of research proposals and final reports, a conflict of interest might arise as a result of direct, or indirect, personal, academic, financial or working relationships.

The acid test is whether a member of the public, knowing the facts of the situation, might reasonably think the judgement could be influenced by the potential conflict of interest.

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Identifying and managing COI: best practices

- ENERI Classroom, Research Ethics and Research Integrity Manual COIs managed responsibly

- Path2Integrity learning card on COIs (card Y7)

- Research Ethics Program of University of California educational resource on COIs

- Office of Research Integrity (ORI) has collected resources on COIs and commitment

- Committee on Publication Ethics (COPE) guidelines addressing COIs in publication ethics

- International Committee of Medical Journal Editors (ICMJE) disclosure of interest form

Source: Embassy of Good Science, 2022

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5d | Outputs and impact

Pathways to impact

Impact – definition of impact – uptake in policy, systems

CEI – funders' directive (risk of tokenism)

Post study reporting

PHRC role in codesign dissemination, engagement e.g. w/programmes

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Research impact

Research impact: 'the demonstrable contribution that excellent research makes to society and the economy.'
- academic impact: contribution research makes in shifting understanding, advancing scientific method, theory and application across/within disciplines
- economic and societal impact: contribution research has on society and the economy, and its benefits to individuals, organisations or nations.

Research impact can include:
- instrumental impact: influencing the development of policy, practice or services, shaping legislation and changing behaviour
- conceptual impact: contributing to the understanding of policy issues and reframing debates
- capacity building through technical and personal skill development.

Uptake in policies and systems

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Research outputs and impact

PHRC role in codesign?

- Dissemination

- Engagement

- Other stakeholders? Health programmes?

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Plenary: Reflections/ feedback (codesign web package)

1. Feedback on training

2. Next steps

- Codesign

- Commentary

- Formalising/progressing further work
  on adaptive research governance
  w/PHRC eg with STIAS

stias

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