Ethics in Health Research

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Course Overview

The *Ethics in Health Research Course* provides a focused exploration of the ethical frameworks, principles, and processes that guide health research in South Africa. Centred on the Ethics in Health Research: Principles, Processes and Structures (2024, Version 3.1), it examines how ethical standards protect participants, promote justice, and ensure that studies are scientifically sound and socially responsible. Participants learn about South Africa's ethics infrastructure, the role of research ethics committees, and the application of ethical principles in research involving human participants and biological materials.

The course also addresses topics such as informed consent, data protection, and emerging issues like digital health research, data sharing, and community engagement. Through theory and practical examples, participants develop the skills to identify and manage ethical challenges, fostering integrity, accountability, and respect in health research.

Certification

- Delegates are required to complete a final assessment with at least 70% accuracy.
- Upon successful completion of the course, the delegate will be given access to the Ethics in Health Research Certificate of Completion, valid for 3 years.

CPD Points

- CPD points will be issued with the certificate of completion.

Target Audience

The target audience includes investigators and research professionals involved in studies on biological, clinical, psychological, or social welfare issues, including disease causes, human–related processes, healthcare delivery, and the development of new medicines, interventions, and health technologies.

It is also suitable for ethics committee members, regulatory personnel, students, and healthcare professionals seeking to strengthen their understanding of ethical principles in health research.

Duration

- The classroom training is one (1) full day (from 08h30 to 16h00).
- The online training takes approximately 6 hours to complete.

Cost

Classroom

WHC	R1,100.00	No Vat
Wits	R1,265.00	Vat Incl
Private	R1,420.25	Vat Incl

In–house training will be considered, subject to viability.

training@academicadvance.co.za
+27 11 274 9431/9317/9221
31 Princess of Wales Terrace, Parktown, 2193
https://www.academicadvance.co.za
academic advance
Wits Health Consortium (Pty) Ltd

Cost

Virtual (By prior arrangement)

WHC	R690.00	No Vat
Wits	R793.50	Vat Incl
Private	R793.50	Vat Incl

eLearning

WHC	R370.00	No Vat
Wits	R425.50	Vat Incl
Private	R471.50	Vat Incl

Learning Outcomes

Introduction to Ethics in Health Research

- Understand the definition and importance of ethics in health research.
- Recognise how ethical conduct protects human dignity, promotes justice, and ensures research benefits individuals and communities.
- Appreciate the South African context for ethical research, including legal and constitutional protections.

Module 1: The South African Context

- Learn about constitutional rights and protections for research participants in South Africa.
- Understand the importance of informed consent and freedom of expression in research.
- Recognise the need to respect indigenous cultures, traditional philosophies, and community knowledge systems.
- Identify unique aspects of health research in South Africa, such as disease burden, diversity, and oversight structures.

Module 2: The Guidelines and Health Research Ethics Infrastructure

- Become familiar with the 2024 South African Ethics in Health Research Guidelines and their role as the national benchmark.
- Understand the purpose and key features of the guidelines, including protection of participants, guidance for RECs, and promotion of fairness and justice.
- Learn about the National Health Research Ethics Council (NHREC) and its responsibilities.
- Recognise the importance of independent ethics review for all health research protocols.

Module 3: Guiding Principles for Ethical Research

- Explore foundational ethical principles: beneficence, non–maleficence, distributive justice, and respect for persons.
- Understand the importance of scientific integrity, stakeholder engagement, and a favourable risk–benefit ratio.
- Learn about fair selection of participants, informed consent, ongoing respect for participants, and researcher competence.
- Apply these principles to real–world case studies and research scenarios.

Module 4: Norms and Operational Processes for Ethics Review

Preparing for REC Submission

- Researchers must ensure their study protocol is scientifically sound, feasible, and aligns with disciplinary standards.
- The protocol should clearly state the importance, novelty, and achievable aims and objectives.
- A thorough literature review and previous studies must be included.
- Researchers must be suitably qualified, and the data management and dissemination plans should be appropriate.
- Any potential or existing conflicts of interest must be addressed.

Module 4: Norms and Operational Processes for Ethics Review

Ethical Basis for Decision–Making

- Research Ethics Committees (RECs) review protocols objectively, focusing on ethical implications rather than personal preferences.
- Scientific review should precede ethics review, and the scientific review report should accompany the protocol to the REC.
- This process fosters transparency and avoids duplication.

Scientific and Ethical Review Before Approval

- Before REC approval, protocols undergo several reviews:
  - Scientific review (methodology, aims, objectives)
  - Institutional and site permissions
  - Social and methodological ethics
  - Scholarly review standards

Inclusion and Exclusion Criteria

- Criteria must be clear, explicit, and justified, especially for vulnerable participants.
- Sample size must be justified to ensure adequate study power.
- For animal research, the choice of species and model must be justified.

Community and Stakeholder Engagement

- Engagement with communities and stakeholders is essential for ethical and scientific quality.
- Protocols should define how stakeholders are identified, engagement methods, timing, and frequency.
- Justification for including specific groups and plans for adapting engagement strategies must be included.
- Engagement should be properly resourced and documented.

Ethical Recruitment and Enrolment

- Recruitment materials must clearly explain the study's purpose, risks, and benefits.
- All recruitment materials must be included in the protocol submission.
- Fairness and transparency are critical; avoid selection bias and ensure voluntary participation.
- Recruitment should protect privacy and respect confidentiality.
- Power dynamics (e.g., student/lecturer, patient/doctor) must be managed to protect voluntariness.

Risk and Benefit Assessment

- Research is ethically acceptable only when potential benefits outweigh risks.
- RECs assess whether harms and benefits are clearly identified, evaluated, and described.
- Risks must be reasonable and justifiable relative to anticipated benefits and the importance of knowledge gained.
- Risk mitigation plans, including distress protocols and support services, must be in place.

Compensation and Reimbursement

- All participation costs should be covered; no participant should incur a financial burden.
- Compensation should be fair and not impair judgment.
- Inducements must be proportionate and justified, especially in high–risk studies.
- The TIE method (Time, Inconvenience, Expenses) is used to calculate compensation.
- Special considerations apply for minors and incomplete participation.

Privacy, Confidentiality, and Data Management

- Privacy is a constitutional right; confidentiality is an ethical obligation.
- Informed consent is required for any use of personal information.
- Protocols must outline how privacy and confidentiality will be managed and safeguarded.
- Data types include anonymous, anonymised, coded, and de–identified data, each with specific handling requirements.

Vulnerable and Dependent Populations

- Special safeguards are required for vulnerable groups (minors, women, older adults, those with impairments, inmates, collectivities).
- Voluntariness and informed consent are critical.

Vulnerable and Dependent Populations

- Power imbalances must not influence participation.
- Research procedures must accommodate physical, sensory, and communication needs.

Ethical Requirements for Collectivities

- Engage respectfully with group leaders and representatives.
- Obtain permission before approaching individuals.
- Ensure informed consent and fair sharing of benefits and burdens.
- Clarify data ownership, publication rights, and provide feedback to the group.

Mandatory Reporting and Legal Duties

- Researchers must understand when and what to report, especially regarding children and vulnerable persons.
- There is no general legal duty to report a crime, except when there is a credible threat of harm to another person.

Module 5: Human and Animal Biological Material and Data for Research

- Understand the ethical and legal requirements for collecting, storing, and using human biological material (HBM) and data.
- Learn about informed consent models, levels of identifiability, and implications of anonymisation.
- Recognise responsibilities associated with storage, retention, and withdrawal of consent.
- Become familiar with biosafety, data repositories, and fair attribution of credit.
- Understand the Protection of Personal Information Act (POPIA) and its impact on research data management and sharing.
- Explore ethical considerations in genetic and genomic research, including consent, privacy, and management of sensitive findings.