Ethics in Health Research

Research ethics specify the basic norms and values of the research community. They are based on the general ethics of science; just as general ethics are based on the morality of society at large. Research involving human subjects or participants introduces unique and complex ethical, legal, social and political issues.

Research ethics is specifically focused on the examination of ethical issues that are raised when people are involved as participants in research.

Description

The **Ethics in Health Research** course is designed to provide delegates with a comprehensive understanding of ethical considerations within the context of health research, with a specific focus on the unique challenges and nuances present in South Africa. This course aims to equip students, researchers and healthcare professionals with the knowledge and skills necessary to navigate the complex ethical landscape of health research in the country.

Available as online training

Content

Introduction to Ethics in Health Research
Module 1: The South African Context
Module 2: The Guidelines and Health Research Ethics Infrastructure
Module 3 : Guiding Principles for Ethical Research
Module 4: Norms and Operational Processes for Ethics Review
Module 5: Human and Animal Biological Material and Data for Research
Final Assessment

Cost

Online - R 450(VAT incl.)

WHC Divisions | Projects:
Online - R 350

For group discounts, please contact us at:
training@academicadvance.co.za

Duration

The online training takes approximately 6 - 8 hours to complete.

Target Audience

Investigators and individuals involved in research that advances knowledge of biological, clinical, psychological, or social welfare issues, including human-related processes, disease causes and effects, environmental impacts on humans, healthcare delivery improvements and new pharmaceuticals, medicines, interventions, devices and health technologies.

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 Certificate of Completion.

CPD Points

CPD points will be issued with the certificate of completion.

In-House Training

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

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Training Topics

Introduction to Ethics in Health Research

- The **introduction** covers ethics in health research as the foundation of responsible and respectful studies, with a focus on the South African context.
- Ethics is defined as the study and practice of moral principles that guide behaviour, including decision-making and conduct. The module highlights how ethics promotes human dignity, justice, and wellbeing, and introduces key concepts such as autonomy, respect, equality, and protection from harm.
- Delegates are introduced to how ethical principles are applied in health research to ensure safety, fairness, and quality of life.
- Informed consent is emphasised as a legal and ethical requirement, and the importance of upholding human dignity is explored through culturally sensitive and inclusive research practices.

Module 1: The South African Context

- **Module 1** introduces the ethical and legal foundations of health research in South Africa, focusing on constitutional protections like Section 27(1) (access to health care) and Section 12(2) (protection from non-consensual experimentation). It highlights the importance of academic freedom, respect for indigenous knowledge, and culturally appropriate consent, alongside meaningful community engagement and fair benefit-sharing.
- The principle of Ubuntu is central, promoting ethical decision-making rooted in community wellbeing and interconnectedness.
- The module also outlines South Africa's unique research context, shaped by cultural diversity, historical exploitation, and vulnerable populations. It introduces the Protection of Personal Information Act (POPIA), which governs data use in research, requiring informed, specific, and voluntary consent.
- Researchers must ensure data is relevant, secure, and used only for its stated purpose under legitimate interest, with mandatory ethical oversight and compliance with national guidelines.

Module 2: The Guidelines and Health Research Ethics Infrastructure

- **Module 2** outlines the 2024 Ethics in Health Research Guidelines, which set national standards for research involving humans, animals, and biological materials. It emphasises community engagement, transparency, and accountability, especially for vulnerable populations. The National Health Act (NHA) defines health research broadly, and the NHREC oversees compliance, registers RECs, and promotes Ubuntu-based ethics.
- Institutions must have access to a registered REC, which reviews protocols prospectively, retrospective approval is not allowed.
- Ethics review includes risk, benefit analysis across human, animal, and environmental dimensions. Even public or observational data may require review, depending on privacy and publication intent.
- The module reinforces compliance with POPIA and national regulations to ensure secure, lawful, and relevant use of personal data.

Module 3: Guiding Principles for Ethical Research

- **Module 3** covers the core ethical principles guiding responsible health research: beneficence, non-maleficence, distributive justice, and respect for persons, including dignity, autonomy, and protection of the vulnerable. It emphasises that informed consent must be voluntary, clear, and ongoing, and that research should address South Africa's health priorities and promote public wellbeing.
- The module highlights the need for scientific integrity, stakeholder engagement, and fair participant selection, alongside risk, benefit analysis and respect throughout the study. Researchers must be ethically trained, appropriately qualified, and accountable for participant safety, with protocols allowing withdrawal at any time and ensuring ongoing monitoring of wellbeing.

Module 4: Norms and Operational Processes for Ethics Review

- **Module 4** covers key ethical considerations in research design and implementation. Delegates will explore why scientific review must precede ethics review to ensure sound methodology and avoid duplication.
- They will learn to justify inclusion and exclusion criteria, especially for vulnerable groups, and avoid convenience sampling.
- The module highlights ethical, transparent, and context-sensitive recruitment, with a focus on community and stakeholder engagement to build trust and support ethical enrolment.
- Delegates will also explore best practices in describing research procedures, maintaining researcher competence, and conducting risk, benefit analyses that consider participants, researchers, and society.
- They will learn to distinguish between reimbursements and inducements, apply the TIE method for fair compensation, and uphold privacy and confidentiality as constitutional rights.
- Protocols must protect data, preserve anonymity, and prioritise group confidentiality where needed.

Informed Consent, Vulnerability and Incapacity

- This **sub-module** covers informed consent and vulnerability in research. Delegates will explore how to obtain consent that is voluntary, ongoing, and culturally appropriate, with clear communication of risks, data use, and participant rights. They will learn about various consent types, including written, verbal, electronic, proxy, deferred, and postmortem, and understand when waivers may be ethically justified for minimal risk studies.
- The module introduces ethical strategies for working with vulnerable groups, such as minors, women, older persons, and dependent populations, including how to apply parental permission, assent, and proxy consent appropriately.
- Delegates will also explore ethical considerations in collective research, including the need for leader consent and fair benefit sharing, and how to ensure voluntariness in studies involving inmates or dependents.
- They will learn how to uphold privacy, manage data risks, and meet legal obligations under the Children's Act, particularly in cases of abuse or neglect. This sub-module equips researchers to navigate complex consent scenarios with sensitivity, legal awareness, and ethical integrity.

Training Topics

Considerations Specific to Research Methodologies or Contexts

- This **sub-module** covers ethical review tailored to the research context and methodology, not limited to clinical models.
- It highlights the need for disciplinary expertise in RECs, especially for social science and qualitative research, which prioritises context, trustworthiness, and understanding of social realities over statistical rigour.

Major Incidents and Research

- This **sub-module** covers ethical research during public health emergencies, where urgency must not override ethical standards. Delegates will explore how to apply the NDoH 2024 and SA GCP 2020 guidelines even in the absence of formal SOPs, and learn to navigate challenges related to consent, capacity, and vulnerability in emergency contexts.
- They will examine how rapid ethics review can be conducted within 36 to 48 hours, while still ensuring thoroughness and participant protection.
- Delegates will also learn how to balance information sharing with confidentiality, and engage stakeholders in an inclusive and sustained manner. The module covers ethical approaches to research in intensive and terminal care, including alternative consent methods, strict safeguards, and realistic expectations.
- Any deviations from standard ethics must be carefully justified, and delegates will gain insight into how to uphold ethical standards under pressure.

Traditional Medicine, Indigenous Knowledge and Complementary Medicines

- This **sub-module** introduces how to ethically conduct research involving traditional medicine and Indigenous Knowledge (IK), ensuring practices are culturally respectful, non-harmful, and aligned with community values.
- The module highlights the importance of protecting participants and promoting ethical engagement with Indigenous communities.
- It also covers the role of Research Ethics Committees (RECs) in preventing intellectual property exploitation and ensuring compliance with legal frameworks such as the Nagoya Protocol, Biodiversity Act, and Indigenous Knowledge Act (2019). Research involving Complementary and Alternative Medicines (CAMs) like Ayurveda and Chinese medicine must follow ethical standards and comply with SAHPRA's SA GCP 2020 and NDoH 2024 guidelines.

Data Science Research and Artificial Intelligence (AI)

- This **sub-module** introduces ethical considerations in data science and AI health research, where the focus shifts from human participants to data subjects.
- Delegates will explore key concerns such as anonymity, informed consent, data reliability, and algorithmic bias, with an emphasis on protecting individuals throughout the data lifecycle.
- Research Ethics Committees (RECs) must assess issues like secondary data use, privacy, and compliance with POPIA.
- AI research, especially in clinical settings, must ensure fairness, transparency, safety, and accountability. Ethical review is required even when using simulated data, and researchers must address local relevance, language diversity, and post-mortem data protection.

General Topics

- This **sub-module** covers ethics in international and high-risk research. Delegates will learn that international studies in South Africa require local REC approval, SA GCP 2020 compliance, and formal agreements for roles and benefit-sharing. Deception is only allowed with REC approval and post-study disclosure.
- Online-only studies may be exempt if POPIA compliance is shown, and South African researchers abroad need dual ethics approval.
- It also addresses consent and privacy for audio-visual recordings, especially of minors, and clarifies that novel therapies for individual use are not considered research.
- Sponsors must insure participants against research-related injuries, with ex gratia payments expected under SA GCP 2020. Participants retain legal rights, and malpractice claims are handled through professional liability insurance.

Module 5: Human Biological Material and Data for Research

- **Module 5** focuses on ethical research involving Human Biological Material (HBM), such as DNA, tissues, and blood products.
- Delegates will explore different consent models including specific, tiered, and broad consent, with added protections for minors and individuals with mental incapacity.
- They will learn how anonymisation impacts participant rights, and why secondary use of HBM requires ethics review and possibly renewed consent.
- Delegates will also examine the responsibilities of custodians in maintaining confidentiality, securing code keys, and using Material Transfer Agreements.
- The module covers ethical management of biobank closure, HBM export permits from the National Department of Health, and governance of data repositories.
- Delegates will understand that HBM and data are not privately owned, and researchers have stewardship duties.
- In genetic and genomic research, they will explore ethical issues around consent, safety, long-term monitoring, return of results, and handling incidental findings, especially in relation to families, identifiable groups, and children.