



PHARMA-ETHICS

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1 June 2026

Dear Colleagues

RE: Notice regarding the NDoH 2024 Research Ethics Guidelines Training Requirements

Our letter dated 27 January 2026 refers.

It has come to the Committee's attention that uncertainty remains regarding Pharma-Ethics' Research Ethics training requirements.

The purpose of this communication is to clarify Pharma-Ethics' requirements regarding training in research ethics and the Department of Health's *Ethics in Health Research: Principles, Processes and Structures* (2024, 3rd Edition).

Background

The National Department of Health's *Ethics in Health Research: Principles, Processes and Structures* (2024, 3rd Edition) places significant emphasis on the ethical conduct of research involving human participants and outlines the responsibilities of researchers, Research Ethics Committees (RECs), institutions, and sponsors in ensuring compliance with accepted ethical standards.

Section 5.4 of the NDoH Ethics Guidelines stipulates the requirement for additional training in health research ethics **alongside** Good Clinical Practice (GCP) training. Accordingly, Pharma-Ethics expects all individuals involved in the conduct, oversight, administration, or review of health research involving human participants to obtain appropriate research ethics training.

Rationale for Research Ethics Training

The following principles underpin this requirement:

1. The NDoH Ethics Guidelines (2024, 3rd Edition) require additional training in health research ethics alongside GCP training.
2. All REC members, REC administrators, researchers, and students undertaking research involving human participants are expected to complete theoretical training in research ethics to ensure familiarity with applicable ethical principles and regulatory expectations, including those outlined in the NDoH Ethics Guidelines.



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3. Researchers are expected to possess the necessary knowledge, skills, expertise, and competence to conduct research involving human participants. This includes an appropriate scientific background, discipline-specific expertise, and adequate training in research ethics.
4. While the South African Good Clinical Practice Guidelines (2020) provide guidance on the design, planning, management, conduct, monitoring, and regulation of clinical trials, they do not comprehensively address the ethical principles underpinning ethical research conduct. These principles are outlined in the Department of Health's *Ethics in Health Research: Principles, Processes and Structures* (2024, 3rd Edition).
5. The South African GCP Guidelines (2020) state that: "All role players involved with clinical trials should also be familiar with other national and international guidelines, including but not limited to the following current versions or their successors: Department of Health's Ethics in Health Research: Principles, Processes and Structures."
6. Research ethics training must be renewed at least every three (3) years to ensure ongoing familiarity with evolving ethical, legal, and regulatory requirements.
7. Although the NDoH Ethics Guidelines do not specifically define the term "researcher" for training purposes, the SA GCP Guidelines require all role players involved in clinical trials to be familiar with the Ethics Guidelines. Consequently, Pharma-Ethics extends the requirement for research ethics training to all individuals who must complete GCP training. The same principle applies to non-clinical health research involving human participants, irrespective of whether GCP training is formally required.

Effective Date

All researchers involved in research reviewed by Pharma-Ethics are expected to provide evidence of training on the *Ethics in Health Research: Principles, Processes and Structures* (2024, 3rd Edition) by **1 January 2027**.

Previous Communication Regarding Virtual Training

In previous correspondence, Pharma-Ethics advised that virtual ethics training would be accepted, provided that such training complies with the South African Health Products Regulatory Authority (SAHPRA) requirements for virtual training as outlined in the guidance document:

<https://www.sahpra.org.za/wp-content/uploads/2024/04/SA-GCP-training-Post-COVID-pandemic.pdf>

Despite this clarification, Pharma-Ethics continues to receive numerous queries regarding the acceptable content, format, duration, and certification requirements for ethics training. In addition, training certificates are frequently submitted that do not meet Pharma-Ethics' minimum requirements.

Accordingly, this communication provides detailed guidance on Pharma-Ethics' research ethics training requirements, which will take effect on **1 January 2027**.



Autonomy of Research Ethics Committees

Pharma-Ethics acknowledges that training requirements may differ among Research Ethics Committees and institutions. We further note that, in accordance with the National Health Research Ethics Council's (NHREC) statutory mandate, the NHREC does not make determinations regarding the specific curricula, course content, duration, delivery format, or certification requirements for research ethics training.

The NHREC has confirmed that these matters remain within the discretion of individual RECs and their affiliated institutions. Researchers are therefore advised to ensure that any ethics training undertaken satisfies the requirements of the REC responsible for reviewing and overseeing their research.

Pharma-Ethics Minimum Requirements for Research Ethics Training

The following minimum requirements will apply to all health research reviewed by Pharma-Ethics.

1. Persons Required to Complete Training

- The NDoH *Ethics in Health Research: Principles, Processes and Structures* (2024, 3rd Edition) requires Research Ethics Committee (REC) members, REC administrators, researchers, and students undertaking research involving human participants to undergo training in research ethics.
- In addition, the South African Good Clinical Practice (SA GCP) Guidelines (2020) state that all role players involved in clinical trials should be familiar with the NDoH Ethics Guidelines.
- Pharma-Ethics is of the view that training in the NDoH Ethics Guidelines would be beneficial to all individuals involved in the conduct, oversight, management, administration, monitoring, and review of health research. However, we recognise the practical constraints associated with implementing a new training requirement and acknowledge the time and resources required to obtain such training.

Accordingly, the following implementation approach will apply:

- **Investigators** (including Principal Investigators, Co-Investigators, and Sub-Investigators) must provide evidence of training on the NDoH Ethics Guidelines by **1 January 2027**.
- **All other research role players**, including study coordinators, research nurses, monitors, project managers, data managers, and other personnel involved in the conduct of health research, will be granted an extension until **1 January 2028**, or until further clarification is provided by the relevant regulatory authorities regarding the interpretation of the term "researchers" for training purposes.



2. Acceptable Training Formats

Pharma-Ethics will accept both face-to-face and virtual training programmes, provided that the training meets appropriate educational and quality standards.

Training Content: Consistent with the South African Health Products Regulatory Authority (SAHPRA) guidance on virtual GCP training, the following requirements will apply to virtual ethics training:

- Training conducted through virtual platforms (e.g. Zoom, Microsoft Teams, or equivalent platforms) will be accepted provided that:
 - the training is delivered in a structured and appropriate manner;
 - the programme is interactive;
 - active participant engagement and attendance are monitored throughout the course;
 - opportunities for discussion and questions are provided; and
 - a suitably qualified facilitator is present and available for the full duration of the training.
- Hybrid training models that combine self-directed learning with facilitator-led virtual sessions will be considered acceptable, provided that sufficient evidence is available to demonstrate participant completion of the self-study component and meaningful engagement during the interactive component.
- Courses consisting solely of self-paced online modules without real-time interaction, participant engagement, or facilitator involvement will not be accepted.

3. Duration of Training

Pharma-Ethics recognises that the duration of research ethics training may vary depending on the format, scope, and intended audience.

For purposes of demonstrating adequate coverage of the NDoH Ethics Guidelines, the following minimum requirements will apply:

- A standalone ethics training programme should be broadly equivalent in depth and content to recognised research ethics training programmes.
- A minimum of **one full day of interactive training** will be accepted where participants are required to complete a structured self-study component before attending the interactive session and evidence of completion is available.
- Where Ethics and Good Clinical Practice (GCP) training are combined into a single programme, the following minimum requirements will apply:
 - the training must be conducted in a virtual or face-to-face interactive format;
 - the total course duration must be at least **three days**; and
 - a minimum of **one full day** must be dedicated specifically to the Department of Health's *Ethics in Health Research: Principles, Processes and Structures* (2024, 3rd Edition).

4. Accreditation

To ensure the quality and credibility of training programmes, Pharma-Ethics strongly prefers that research ethics training be accredited by the **Health Professions Council of South Africa (HPCSA)** or an equivalent recognised professional accreditation body.

Training providers should be able to demonstrate that the course content is current, aligned with the NDoH Ethics Guidelines (2024, 3rd Edition), and presented by suitably qualified facilitators with expertise in health research ethics.



Course content

- The following content must be included:
 - The role of the NHREC
 - The context of the 2024 Ethics Guidelines
 - The definition of Health Research
 - The basic principles applicable to biomedical research
 - The eight key norms for ethics research with human participants
 - Ethical Basis for decision-making in the review process
 - The process for obtaining informed consent
 - Waiver of consent
 - Formats of Consent (Written, electronic, remote, proxy, deferred)
 - Vulnerability
 - Defined in the South African Context
 - Contextual Circumstances
 - Review Criteria
 - Minors
 - Children and Adolescents without Guardians
 - Minor's Independent Consent
 - Women
 - Elderly Persons
 - Persons in a Dependent Relationship
 - Collectivities/Communities
 - Social Science Research
 - Types of Research
 - Methodology and Limitations
 - Considerations for Ethics Review of Social Science Research
 - Different Research Methodologies
 - Major Incidents
 - Intensive Care Research
 - Terminal Care Research
 - Traditional Medicines Research
 - Complementary and Alternative Medicine Research
 - Insurance Against Research-Related Injury
 - Health Data Science Research
 - Artificial Intelligence Research
 - Human Biological Materials
 - Definition and Examples
 - Purposes for Collecting HBM
 - Different Consent Models
 - Secondary Use of HBM
 - Cell Lines
 - Genetic and Genomic Research



Course Details

1. Virtual training courses meeting the above requirements are available from various service providers
2. To assist researchers, Pharma-Ethics is offering a 2-day, CPD-accredited courses (12 ethics points). The courses are:
 - Face-to-face in Pretoria (maximum eight participants)
 - Face-to-face in the Western Cape (maximum 12 participants)
 - On-site training (minimum 10 participants)
3. The courses will focus on the Ethics Guidelines and do not replace GCP training.
4. If you are interested in any of the above, please contact:
 - Marzelle Haskins – marzelle@pharma-ethics.co.za and copy Sumae Welgemoed – monitoring@pharma-ethics.co.za for more information.

