

27 January 2026

Dear Colleagues

RE: NDoH 2024 Research Ethics Guidelines Training Requirements

The NDoH Ethics Guidelines (2024), Section 5.4, stipulate the requirement for additional training in health research ethics. The guidelines specifically state that researchers must have additional research ethics training. This is because the SA GCP no longer contains detailed information on Research Ethics, and all health researchers, not just those conducting clinical trials, are required to have ethics training.

The guidelines state the following: *“It is expected that all REC members, REC administrators, researchers, and students who will undertake research with human participants, will ensure they complete theoretical research ethics training to ensure they are familiar with expectations, especially those set out in NDoH 2024, 3rd ed and, for clinical trials, SA GCP 2020. It is expected that researchers complete the required research ethics training before conducting research. Researchers are expected to ensure they possess the appropriate knowledge, skills, expertise, and competence, including a discipline-appropriate scientific background and research ethics training, to conduct studies involving human participants. Health research ethics training is additional to discipline- or profession-specific and GCP training and must include an assessment to provide evidence of more than mere attendance at training.”*

South African GCP Guidelines (2020) stipulate the following: *“Users need to familiarise themselves with the clear alignment between DoH 2015 and SA GCP 2020 so that they design, plan, manage and conduct their clinical trials in accordance with the ethical principles and values that underpin their practical application to clinical trials. These (GCP) guidelines focus on design, planning, management, conduct and regulation of clinical trials involving human participants. They do not repeat the ethical principles that underpin sound and ethical research, as outlined in the Department of Health’s Ethics in Health Research: Principles, Processes and Structures, 2nd edition (2015) (referred to as DoH 2015). **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: 1.2.2.1 Department of Health’s Ethics in Health Research: Principles, Processes and Structures 2nd edition (2015) (referred to as NDoH 2015).**”*



Researchers must receive training on the 2024 Ethics Guidelines in the same way they receive GCP training. Ethics training must cover every section of the Ethics Guidelines.

Training on the Ethics Guidelines must be **renewed every three years**.

The NDoH Ethics guidelines do not define ‘**researcher**’ for training purposes. However, SA GCP requires that all role-players involved in clinical trials should familiarise themselves with the ethics guidelines. Therefore, the requirement for ethics training will be extended to all parties who must obtain GCP training. The same applies to non-clinical health research, even if GCP training is not required.

It is expected that all researchers provide evidence of training on the 2024 Ethics Guidelines by 1 January 2027.

Pharma-Ethics will accept **virtual training** that complies with the **SAHPRA virtual training requirements**. <https://www.sahpra.org.za/wp-content/uploads/2024/04/SA-GCP-training-Post-COVID-pandemic.pdf>

To assist researchers, Pharma-Ethics is offering the following 2-day, CPD-accredited courses (12 ethics points):

- Face-to-face courses in Pretoria
- Face-to-face courses in the Western Cape
- Virtual training
- On-site training

These courses will focus on the Ethics Guidelines and do not replace GCP training.

For more information on the courses, please follow the registration link on our website.

Please contact marzelle@pharma-ethics.co.za for information on **on-site training**.

Regards

The Pharma-Ethics Team

