



PHARMA-ETHICS

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01 September 2025

Dear Colleagues

RE: Update to the 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. The expectation is that researchers should 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, which are 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. Such a course will have to cover every section of the Ethics Guidelines. If the DoH 2024 guidelines are covered in detail as part of an accredited GCP course, we will accept it.





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However, GCP courses that only include a general research ethics topic and references to the 2024 Ethics Guidelines are not sufficient. The Ethics Guidelines address many issues that are pertinent to research in South Africa.

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 are required to obtain GCP training. The same applies to non-clinical health research, even if GCP training is not required.

During the annual stakeholder meeting with the NHREC, the Council indicated that, due to the high demand for training researchers on the above guidelines, it expects the training to be completed by December 2026.

Pharma-Ethics will therefore extend the requirement for training of researchers until December 2026.

We are aware that both SAHPRA and the NHREC are open to **virtual training**; therefore, we will accept CPD-accredited, interactive, virtual training on the 2024 NDoH Guidelines that comply 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 presenting 2-day CPD-accredited (12 points) online, face-to-face, and onsite courses. **These courses will focus on the Ethics Guidelines and do not replace GCP training.**

For more information on the online and face-to-face 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



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