PHARMA-ETHICS

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Ethics training required by NDOH 2024

Dear Colleagues

Herewith, information outlining the requirements for ethics training by researchers.

PLEASE NOTE: The NDoH 2015 ethics guidelines have been replaced with the NDoH 2024 ethics guidelines.

Pharma-Ethics is registered with the National Health Research Council (NHREC), and our registration is renewed every five years, after an audit by the NHREC. Our current registration is until 30 November 2027

If any REC registered with the NHREC does not comply with the NDoH 2024 ethics guidelines, their registration with the NHREC can be suspended and that REC may not be able to continue reviewing research proposals.

Failure to comply with training requirements risks the suspension of registered RECs, including the Pharma-Ethics REC, due to non-compliance.

The requirement that researchers be trained on the ethics guidelines is first set out in NDOH 2024 and second in GCP 2020.

First, NDoH 2024 (Section 5.4) stipulates additional health research ethics training requirements. This is because SA GCP no longer contains detailed information on research ethics, and all health researchers, not just those who conduct clinical trials, must have ethics training. NDoH 2024 states 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 have the appropriate knowledge, skills, expertise, competence, including discipline-appropriate scientific background and research ethics training to conduct studies involving human participants*." NDOH 2024 states, "*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*".

Secondly, GCP (2020) stipulates the following: *"It is vital for users 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 following the ethical principles and values that underpin their practical application to clinical trials. These (GCP) guidelines focus on designing, planning, managing, conducting and regulating clinical trials involving human participants. They do not repeat the ethical principles that underpin sound and ethical research 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 DoH 2015)."

Also, GCP 2020 makes continuous reference to NDOH guidance, of which the following are

Compliance with the training requirements set out in NDOH 2024 requires the following:

- Training must cover all sections of DoH 2024 and be 'assessed'.
- If DOH 2024 is covered in detail as part of an accredited GCP course and included in the training certificate, it will be accepted. A 2-day course is not sufficient to cover both GCP and Ethics training. If GCP courses only include general research ethics topics and a brief reference to DoH 2024, it is unlikely to meet the requirement of "*theoretical research ethics training to ensure (familiarity) with expectations, especially those set out in NDoH 2024 3rd".*
- The training duration should align with the prescribed outcomes or unit standards (approximately 10 hours / 2 days).
- HPCSA should accredit the training content.
- Training on NDOH 2024 should be renewed regularly, e.g. every three years.
- Virtual methods (via Zoom, Teams, etc.) will be acceptable, provided that the training is interactive, active engagement of participants is monitored, and a full-time facilitator (qualified to conduct training) is available for questions and answers throughout the duration.

For more information, please contact marzelle@pharma-ethics.co.za