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

As you are aware, 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 PharmaEthics REC, by the NHREC due to non-compliance.

The requirement for training of researchers on the ethics guidelines is set out *firstly* in NDOH 2024 and *secondly* in GCP 2020.

Firstly, NDoH 2024 (Section 5.4) stipulates the requirement for researchers to have additional health research ethics training. 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 the following: "*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 important 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 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 2 nd edition (2015) (referred to as DoH 2015)." Also, GCP 2020 makes continuous reference to NDOH guidance of which the following are examples:

- Ethical principles of beneficence and non-maleficence, distributive justice (equity) and respect for persons (dignity and autonomy) govern all clinical trials conducted in SA; discussed in detail in 2.1 of DoH 2015
- Where proposed participants are incapable of providing consent e.g. because of loss of consciousness, different procedures may apply; see 3.2.4.3 of DoH 2015
- In clinical trials involving minors, prior documented parental permission to approach the minor to invite participation must be obtained before approaching the minor. The minor chooses whether to participate and provides assent to indicate an affirmative answer; see 3.1.9 and 3.2.2 of DoH 2015 for detailed information
- Using incentives to attract potential participants needs careful consideration. Incentives should not cause a person to ignore, minimise or undervalue the risks posed by the trial; see 3.1.7 DoH 2015 guidelines for more details
- External circumstances like low levels of literacy and formal education, advanced age, young age, personal and socio-economic circumstances, including significant poverty and poor access to health care, may increase vulnerability of South Africans; see 3.2 of DoH 2015 for detailed discussion.
- Minors (younger than 18 years) are regarded as vulnerable persons due to their lack of legal capacity (See 3.2.2 of DoH 2015 for detailed discussion). Minors should participate in research only where their participation is indispensable to the research, i.e. the research cannot deliver the desired outcomes if adult participants were to be used instead (see 3.2.2.1 of DoH 2015).
- Adults who are factually incapable of giving informed consent should participate in research only when their participation is indispensable to research. In such cases proxy consent may be appropriate as detailed in 3.2.4 of DoH 2015.
- The investigator is responsible for ensuring that an adequate information package, in an acceptable format appropriate for the South African context, is available for use in the process of seeking informed consent from participants to participate in the clinical trial (as described in 3.1 of DoH 2015).

For Pharma-Ethics to comply with the training requirements set out in NDOH 2024, the following is important:

- Researchers should take part in training on NDOH 2024 which cover all sections of DOH 2024, and is 'assessed'.
- If DoH 2024 is covered in detail as part of an accredited GCP course, this is acceptable. However, it is not sufficient if GCP courses only include general research ethics topics and brief references to DOH 2024 because this is unlikely to meet the requirement of "*theoretical research ethics training to ensure (familiarity) with expectations, especially those set out in NDoH 2024 3rd".*
- Training on NDOH 2024 should be renewed regularly e.g. every three years.

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- Pharma-Ethics will allow a grace period until the end of 2025 for researchers who have up-to-date GCP training to meet the requirements for ethics training. For researchers who are not involved in clinical trials and do not have current GCP certificates, a grace period of 6 months is allowed

As SAHPRA and the NHREC are open to virtual training we will accept interactive virtual training, with proof of attendance and a training certificate.

Training:

To assist researchers, and other relevant parties in this regard, Pharma-Ethics will do the following:

- Offer a monthly, CPD accredited, 2-day course in Pretoria ○ Offer a 6-weekly CPD accredited, 2-day course in Cape Town. ○ Start such offerings at the end of March 2025.
- Ensure that the **course will focus on NDOH 2024 (and does not replace GCP training for researchers conducting clinical trials).**
- Accommodate initially, a maximum of 20 face-to-face and 10 online attendees to ensure the training is interactive and active engagements of online participants can be monitored.
- Consider providing training at sites or institutions with a minimum of 10 face-to-face attendees but limited to Gauteng and Cape Town.
- Consider training over weekends. ○ Introduce such training at a reduced rate to cover the time and expenses of the facilitator(s) and any direct expenses related to the training.
- Ensure that for non-clinical trial researchers, the course will be sufficient (i.e. additional GCP training is not required).

For more information about the training, please refer to the Training Information Brochure or contact marzelle@pharma-ethics.co.za for information on the training dates, venues and costs.

Your comments are most welcome, as we strive to meet the NDOH 2024 requirements on ethics training, promote ethical research and maintain our registration with the NHREC.

Regards

The Pharma-Ethics Team