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# SOUTH AFRICAN ETHICS IN HEALTH RESEARCH GUIDELINES (2024, 3RD EDITION) TRAINING CONTENT

PLEASE NOTE: This training does not replace GCP training required for clinical trials and must be done in conjunction with GCP training at an accredited service provider.

# CONTENT

# 1. Ethics and Research

- a. Research involving human participants
- b. Ethical Research Review
- c. Purpose, Status and Structure of the Guidelines

# 2. Guiding Principles for Ethical Research:

- a. Ethical Principles
- b. Role of Ethics Principles
- c. Key Norms for Ethical Research with Human Participants
  - i. Relevance and value II.
  - ii. Scientific integrity
  - iii. Stakeholder Engagement
  - iv. Favourable Risk-Benefit Ratio
  - v. Fair Selection of Participants
  - vi. Informed Consent
  - vii. Respect
  - viii. Researcher Competence and Expertise

#### 3. Norms and Operational Processes for Ethics Review:

- a. Ethical basis for decision-making in the review process
- b. Vulnerability and Incapacity
- c. Considerations specific to research methodologies or contexts.
- d. Special Topics

#### 4. Human Biological Material and Data for Research a. Collection of HBM

- a. Introduction to HBM research
- b. Databases, storage and access
- c. Genetic and Genomic Research

# **5. Research Ethics Committees**

- a. Governance Framework
- b. Role of Research Ethics Committees
- c. Education and Training in Research Ethics

# 6. Health Research Ethics Infrastructure

## **COURSE INFORMATION:**

- 2-Days.
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- Face-to-Face:
  - $\circ$  Gauteng and Cape Town (see registration form for dates)  $_{\circ}$
- **Online** (limited availability, see registration form for dates)
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- On-site: For sites or research units aiming to train a minimum of 10 researchers
  - Limited to Gauteng and Cape Town. Please reach out to <u>marzelle@pharma-ethics.co.za</u> for more information
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- Costs: Will be provided on enquiry to marzelle@pharma-ethics.co.za

#### Additional training dates will be made available subject to demand.

Please follow the link for registration:

https://forms.office.com/r/5VB0QvamBY



Once registered, you will receive the training programme