



# PHARMA-ETHICS

## **SOUTH AFRICAN ETHICS IN HEALTH RESEARCH GUIDELINES (2024, 3<sup>RD</sup> 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.**

### **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. Scientific integrity
  - iii. Stakeholder Engagement
  - iv. Favourable Risk-Benefit Ration
  - 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
  - i. Novel, Innovative, Unregistered, and Scientifically Unproven Therapies
  - ii. Data Science Research
  - iii. Artificial Intelligence



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## **4. Human Biological Material and Data for Research**

- a. Collection of HBM
  - i. Consent Models
  - ii. Restrictions
  - iii. Identifiability
  - iv. Secondary Use
  - v. Cell Lines
- b. Database, 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-Day course)**

**TENTATIVE DATES UP TO July 2025:**

**FACE-TO-FACE CENTURION (TBC): 26 – 27 March 2025 & 28 – 29 May 2025**

**Restricted to 15 participants**

**CPD Accredited**

**R3000,00 pp (excl. VAT)**

**FACE-TO-FACE CAPE TOWN (TBC): 7 – 8 May 2025**

**Restricted to 15 participants**

**CPD Accredited**

**Costs: R3500,00 pp (excl. VAT)**



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## **ON-SITE TRAINING –**

**GAUTENG: 9 – 10 April 2025 & 2<sup>nd</sup> Week of June 2025**

**Minimum of 10 attendees**

**Venue and refreshments must be provided**

**CPD Accredited**

**Costs: 10 – 15 participants: R1500 per participant (excl. VAT)**

**16 – 25 participants: R1250 per participant (excl. VAT)**

**25 and more: R1000 per participant (excl. VAT)**

**Costs are negotiable**

**CAPE TOWN: 23 -June 2025 – 3 July 2025 (two days per site)**

**Minimum of 10 attendees**

**Venue and refreshments must be provided**

**CPD Accredited**

**Costs: 10 – 15 participants: R1500 per participant (excl. VAT)**

**16 – 25 participants: R1250 per participant (excl. VAT)**

**25 and more: R1000 per participant (excl. VAT)**

**Costs are negotiable**

## **ONLINE TRAINING:**

**Maximum 10 attendees**

**CPD Accredited**

**Dates: One session per month. Dates will be communicated based on interest**

**Please complete the registration form to be considered for online training.**

**Costs: R1000.00 per person (excl. VAT)**



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**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**