

Good Clinical Practice (GCP) Basic Course for Clinical Staff

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Course Overview

Grounded in the South African Good Clinical Practice (SA GCP) 2020 Guidelines, the *GCP Basic for Clinical Staff Course* provides a comprehensive overview of the ethical and scientific standards required for conducting clinical trials involving human participants.

The course also includes an overview of key international and national ethical guidelines that inform clinical research practice:

- It introduces delegates to the International Council for Harmonisation (ICH) E6(R3) Guideline for Good Clinical Practice, which sets global standards for designing, conducting, recording, and reporting clinical trials.
- In addition, the course introduces the key aspects of the Ethics in Health Research: Principles, Processes and Structures (2024, Version 3.1), South Africa's national guideline that governs ethical conduct in health research.

Certification

- Delegates are required to complete a final assessment with at least 70% accuracy.
- Upon successful completion of the course, the delegate will be given access to the GCP Certificate of Completion, valid for 3 years.

CPD Points

- CPD points will be issued with the certificate of completion.

Target Audience

The target audience includes principal investigators, sub-investigators, study coordinators, clinical trial assistants, research nurses, pharmacists, and other healthcare professionals involved in the conduct of clinical studies.

It is also suitable for regulatory personnel, ethics committee members, and students pursuing careers in health sciences or research.

Duration

The classroom training is two (2) full days (from 08h30 to 16h00).

Cost

Classroom

WHC	R3,120.00	No Vat
Wits	R3,588.00	Vat Incl
Private	R4,588.50	Vat Incl

Virtual (By prior arrangement)

WHC	R2,690.00	No Vat
Wits	R3,093.50	Vat Incl
Private	R3,174.00	Vat Incl

In-house training will be considered, subject to viability.



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Module 1: Introduction to Clinical Research

- Understand the definition and purpose of clinical research and clinical trials.
- Describe the phases of clinical trials (I–IV) and their objectives.
- Distinguish between observational and interventional studies.
- Recognise the importance of data collection, trial design, and the increasing scale of trials.
- Appreciate the role of clinical research in advancing medical knowledge and participant care.

Module 2: Role–players in Clinical Trials

- Identify key role–players: sponsor, Principal Investigator (PI), participants, and multidisciplinary team members.
- Understand the responsibilities of regulatory authorities in clinical trials.
- Recognise how collaboration among team members protects participant rights, safety, and data integrity.
- Describe the roles of Research Ethics Committees (RECs), SAHPRA, and the National Department of Health (NDoH).

Module 3: The Development of ICH GCP

- Explain how historical events shaped Good Clinical Practice (GCP) standards.
- Understand ICH GCP as an international standard for ethical and scientific quality.
- Describe the 11 core principles of ICH E6(R3) GCP and their significance.
- Recognise the consequences of non–compliance with GCP.



Module 4: SA GCP

- Explain the need for country–specific GCP guidelines and how SA GCP aligns with local laws and international standards.
- A detailed explanation is provided for each chapter of the SA GCP Guidelines.
- Understand the SA GCP framework, including investigator and sponsor responsibilities.
- Manage recruitment and protection of vulnerable participants.
- Navigate clinical trial documentation and regulatory authority roles.
- Recognise the impact of regulatory authorities on trial compliance.

Module 5: Informed Consent

- Define informed consent and its importance in clinical trials.
- Identify requirements for valid informed consent, including documentation and the role of an impartial witness.
- Understand who can give consent and the process for vulnerable populations.
- Recognise the need for clear communication, participant understanding, and proper record–keeping.

Module 6: Ethics Guidelines (NDoH 2024)

- Understand the regulation of health research in South Africa.
- Learn the guiding principles, substantive norms, and operational processes for ethics review.
- Recognise the ethical basis for decision–making, including research on minors, women, and vulnerable populations.
- Appreciate the importance of responsible and ethical research conduct in the South African context.

This module provides a high–level overview of the Ethics in Health Research: Principles, Processes and Structures guidelines, but delegates are still required to complete the full training. AA also offers a comprehensive Ethics in Health Research eLearning course for in–depth learning.

