

POST GRADUATE DIPLOMA IN CLINICAL RESEARCH

College of Medicine and Health Sciences | Clinical Research Center

Total Credit Hours: 28

1. Programme Overview

The diploma in clinical research is offered at the Clinical Research Center at the Arabian Gulf University. The program aims to build capacity in clinical research in the Gulf Cooperation Council (GCC) region to support the design, execution, and management of clinical research projects and trials in GCC hospitals and medical research centers.

The diploma program is suitable for graduates in medicine, nursing, pharmacy, life sciences, ethics committee members, regulatory affairs members and other allied disciplines involved in clinical research projects and trials. The diploma provides skills for a career in the diverse and complex field of clinical research management. The one-year Academic Diploma in clinical research provides clinicians-investigators, research nurses, regulatory authorities, members of research ethics committees, and other clinical research professionals a strong foundation in the methods, ethical conduct, coordination, scientific standards, laws and regulations, as well as the operations and management of a clinical research study. It also focuses on the science of pharmaceutical and medical devices development, stem cells and biotechnology products, as well as medical technologies intended for human use.

2. Study Plan

Course Code	Course Title	Credit Hours
One Academic Year — Department Requirements		
CMMSCRP500	RESEARCH METHODS	3
CMMSCRP501	SCIENTIFIC WRITING	3
CMMSCRP502	INTRODUCTION TO RESEARCH ETHICS	2
CMMSCRP503	CRITICAL THINKING	2
CMMSCRP504	MANAGEMENT OF CLINICAL TRIALS	2
CMMSCRP505	RESPONSIBLE CONDUCT IN CLINICAL RESEARCH	2
CMMSCRP506	OPERATIONS OF RESEARCH ETHICS COMMITTEES	2
CMMSCRP507	LEADERSHIP AND PROFESSIONALISM	1

Course Code	Course Title	Credit Hours
CMMSCRP508	REGULATORY ISSUES REGARDING RESEARCH AND PHARMACEUTICALS	2
CMMSCRP509	DRUG DEVELOPMENT	2
CMMSCRP510	PRINCIPLES OF BIOSTATISTICS	1
CMMSCRP511	PRINCIPLES OF GOOD CLINICAL PRACTICE	2
Total Credit Hours		24
Diploma Project		
CMMSCRP608	DIPLOMA PROJECT	4
Total Credit Hours		4
Total Programme Credit Hours		28

3. Course Descriptions

CMMSCRP500 — Research Methods (3 CH)

Provides a foundational understanding of research design, data collection, and analysis in clinical and pharmaceutical research. Covers quantitative and qualitative methodologies, ethical research conduct, and the development of research questions and hypotheses. Develops skills in critically appraising published research and designing research protocols. Introduces literature review techniques, sampling strategies, and key statistical principles. Emphasizes evidence-based research and the interpretation of valid, reliable, and applicable study findings.

CMMSCRP501 — Scientific Writing (3 CH)

Provides a comprehensive introduction to scientific writing in clinical and pharmaceutical research. Focuses on developing clear, concise, and structured scientific communication across academic and regulatory formats. Covers manuscript preparation, research proposal writing, citation standards, and the peer-review publication process. Emphasizes academic integrity, ethical authorship, and effective scientific communication. Develops practical writing skills through guided exercises and feedback to produce professional scientific documents.

CMMSCRP502 — Introduction to Research Ethics (2 CH)

Examines the ethical and philosophical issues arising from research involving human participants in international settings. Explores key topics including standards of care, informed consent, exploitation, and

post-trial benefits. Reviews ethical principles guiding the protection of research participants across diverse contexts. Emphasizes ethical decision-making and responsible conduct in global health research.

CMMSCRP503 — Critical Thinking (2 CH)

Introduces the fundamental principles of critical thinking and logical reasoning. Develops skills in analyzing, evaluating, and constructing arguments with clarity and precision. Emphasizes the assessment of evidence, identification of assumptions, and recognition of logical fallacies. Encourages independent thinking, informed decision-making, and the development of well-reasoned conclusions based on evidence and sound logic.

CMMSCRP504 — Management of Clinical Trials (2 CH)

Focuses on building effective relationships between clinical study teams and research sites. Explores practical aspects of conducting Good Clinical Practice (GCP)-compliant clinical trials. Uses real-world scenarios to develop problem-solving, communication, and trial management skills.

CMMSCRP505 — Responsible Conduct in Clinical Research (2 CH)

Examines the ethical responsibilities of conducting research, including scientific integrity, authorship, peer review, conflicts of interest, data ownership, and intellectual property rights. Develops understanding of research misconduct, its prevention and management, and the impact of conflicts of interest on scientific objectivity and ethical research practice.

CMMSCRP506 — Operations of Research Ethics Committees (2 CH)

Covers the legal and regulatory aspects of ethical review systems in clinical research. Examines the structure and operations of institutional review boards (IRBs), human subject protection programs, and conflicts of interest. Develops understanding of the regulatory and ethical requirements governing research oversight.

CMMSCRP507 — Leadership and Professionalism (1 CH)

Explores the principles of leadership, professionalism, and effective teamwork in research and healthcare settings. Emphasizes interpersonal communication, collaboration, problem-solving, and team dynamics. Helps students identify their strengths and develop skills to contribute effectively to productive and high-performing teams.

CMMSCRP508 — Regulatory Issues Regarding Research and Pharmaceuticals (2 CH)

Examines the legal and regulatory requirements governing clinical trials, with an emphasis on local and international regulatory authorities. Covers protocol submission, Good Clinical Practice (GCP), ethics review processes, conflict of interest, and regulatory compliance.

CMMSCRP509 — Drug Development (2 CH)

Provides a comprehensive overview of the drug development process from discovery to regulatory approval. Covers preclinical evaluation, clinical trial phases, biomarker development, and drug safety assessment. Explores special considerations in vulnerable populations, traditional and complementary medicines, and expedited regulatory pathways.

CMMSCR510 — Principles of Biostatistics (1 CH)

Provides foundational statistical knowledge essential for clinical research. Covers research methodologies, data collection, variable types, and methods for organizing and presenting data. Introduces descriptive statistics and key measures used in medical research, including sensitivity, specificity, relative risk, and odds ratio. Emphasizes the interpretation and application of statistical findings in clinical studies.

CMMSCR511 — Principles of Good Clinical Practice (2 CH)

Introduces Good Clinical Practice (GCP) as the international ethical and scientific standard for conducting clinical research. Covers FDA regulations, ICH-GCP guidelines, and the roles and responsibilities of sponsors, investigators, ethics committees, and regulatory authorities. Emphasizes the application of GCP principles to ensure ethical, compliant, and high-quality clinical research.

CMMSCR608 — Diploma Project (4 CH)

An independent, supervised research project in which students develop and present a research proposal addressing a relevant clinical or health research question. Students apply research methodology, critical appraisal, and scientific writing skills to design a feasible and ethically sound study, demonstrating their ability to integrate knowledge gained throughout the program.