Jordan University of Science and Technology

Faculty of Pharmacy

Doctor Of Pharmacy (Pharm D.) Department

PHMD675 Clinical Training: Clinical Pharmaceutical Research - JNQF Level: 7

First Semester 2024-2025

Course Catalog
4 Credit Hours. Four experiential training weeks in clinical pharmaceutical research. The course focuses on the spectrum of clinical research and the research process by reviewing the literature and highlighting research methods, study design, proposal and protocol preparation, principles involved in the ethical, legal, and regulatory issues in human subject research, in addition to an overview of basic bio-statistical methods involved in conducting clinical research.
Teaching Method: On Campus

Text Book	
Title	Fundamentals of Clinical Trials
Author(s)	Lawrence M. Friedman, Curt D. Furberg and David L. DeMets
Edition	4th Edition
Short Name	Reference 1
Other Information	

Course References

Short name	Book name	Author(s)	Edition	Other Information
Useful Resources	GCP Training modules and cortication: https://gcp.nidatraining.org/	NA	1st Edition	

Instructor	
Name	**Dr. QUSAI AL-SHARE**
Office Location	M5 L-4
Office Hours	Mon : 09:30 - 11:30 Tue : 11:00 - 12:00 Wed : 09:30 - 11:30 Thu : 09:30 - 10:30
Email	qyshare@just.edu.jo

Class Schedule & Room
Section 1: Lecture Time: U : - Room: HOSPITAL Section 2: Lecture Time: U : - Room: HOSPITAL

Tentative List of Topics Covered

Weeks	Topic	References
Week 1	Syllabus & Course Introduction Complete a 12-module GCP training and obtain the certificate of completion with a passing score (80%). Site Orientation: introduction to personnel and departments, site tour, site needed training/regulations/SOPs, GCP training, QA/QC. Provide the title of the research proposal to course instructor, and start writing using the A1 form.	From **Reference 1**, From **Useful Resources**

Week 2	Study start up activities: contracts, budgets, timelines, protocol preparation, ICF, feasibility, essential study documents, IRB and HA submission, role of PI, Sub-I, CRC, research pharmacist, PSV, SIV, IM, IMP handling & accountability, study supplies, study plans, ISF, TMFI. Continue working on the research proposal.	From **Reference 1**
Week 3	Study conduct: pre-screening, consenting, screening, recruitment, dosing, sample collection/handling, data management, query resolution, monitoring, AE reporting, PDs, audits, inspections, documentation. Continue working on the research proposal and start preparing slides from the research proposal for defense at the end of Week 4	From **Reference 1**
Week 4	Study Close-out: COV, archival, supplies return, results reporting, other close out activities. Finalize proposal and slides and submit via email to course instructor. Project defense at JUST by end of this week.	From **Reference 1**

Mapping of Course Outcomes to Program Outcomes and NQF Outcomes	**Course Outcome Weight (Out of 100%)**	**Assessment method**
Utilize the basic principles of good clinical practice (GCP) by completing the assigned training to gain the required theoretical and regulatory knowledge that governs the conduct of clinical trials in human subjects. [1PLO1.1] [1L7C2]	15%	
Describe the steps followed in the planning and conduct of clinical trials in human subjects from startup to close out. [1PLO3.1] [1L7K1, 1L7S3]	40%	
Apply research methodology skills to write a research proposal. [1PLO4.2] [1L7C1]	30%	
Defend a research proposal by the end of the rotation. [1PLO3.2] [1L7C1, 1L7C3]	15%	

Relationship to Program Student Outcomes (Out of 100%)															
PLO1.1	PLO2.1	PLO2.2	PLO2.3	PLO2.4	PLO3.1	PLO3.2	PLO3.3	PLO3.4	PLO3.5	PLO3.6	PLO4.1	PLO4.2	PLO4.3	PLO4.4	PLO5.1
15					40	15						30			

Relationship to NQF Outcomes (Out of 100%)				
L7K1	L7S3	L7C1	L7C2	L7C3
20	20	37.5	15	7.5

Evaluation	
Assessment Tool	**Weight**
Daily Evaluation by Research Preceptor	20%
Complete GCP Training Modules	15%
Research proposal defense	15%
Submit a written research proposal	30%
Quizzes and active learning	20%

Policy

Course Policies	1- Attendance: Students are required to attend at their assigned research center Sunday through Wed every week during their rotation and in coordination with their direct site preceptor. Attendance time follows the center's research preceptor directions and per each center's regulations. Any request for absence on a single day to unforeseen circumstances need to be authorized by both the direct preceptor and the course instructor. 2- GCP training: each student is required to complete the assigned GCP training no later than the end of their first week of the rotation, preferably before the start of the first week. 3- Preceptor's evaluation: each student will be evaluated on daily basis by their assigned preceptor at the center, this evaluation accounts for 20% of the total course grade. 4- Confidentiality: all students are required to follow the center's instructions regarding confidentiality of all research related activities and complete any required training for that. 5- End of rotation: all students who finish their 4th week, are required to report to JUST on the last Thu of their rotation (or as assigned by course instructor) for the project defense presentation and discussions.

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