



The Hebrew University of Jerusalem

Syllabus

GCP - 4TH YEAR - 96403

Last update 05-11-2021

HU Credits: 0

Degree/Cycle: 2nd degree (Master)

Responsible Department: Medicine

Academic year: 0

Semester: 1st Semester

Teaching Languages: Hebrew

Campus: Ein Karem

Course/Module Coordinator: Dr. Ofri Mosenzon MD, MSc

Coordinator Email: ofrim@hadassah.org.il

*Coordinator Office Hours: Thursdays
10:00-14:00*

Teaching Staff:

Prof ofri mosenzon

Course/Module description:

Ethics of clinical research and the rules of Good Clinical Practice (GCP) - that are required for clinical trials in human

Course/Module aims:

- 1) The student will understand the ethical dilemmas of clinical trials in humans.*
- 2) The student will have an in-depth knowledge of the GCP rules and their importance.*
- 3) The student will learn to apply the GCP rules in clinical research in humans.*

Learning outcomes - On successful completion of this module, students should be able to:

- 1) The student will understand the ethical dilemmas that are present during planning and conducting of clinical research.*
- 2) The student will understand the importance of conducting clinical research according to GCP rules and regulations.*
- 3) The student will know the process of Informed Consent.*
- 4) The student will know the process of adverse events reporting in clinical trials.*

Attendance requirements(%):

100%

Teaching arrangement and method of instruction: lectures

Course/Module Content:

- 1) Ethical dilemmas in clinical research.*
- 2) GCP – definition and purposes.*
- 3) GCP history in Israel and abroad.*
- 4) The roles and responsibilities of the partners in clinical trials: the sponsor, the ethic committee, and the investigators.*
- 5) The process of Informed Consent.*
- 6) The process of adverse events reporting in clinical trials.*

Required Reading:

The course's presentations

Additional Reading Material:

The Israeli ministry of health regulation regarding clinical research

Course/Module evaluation:

End of year written/oral examination 100 %

Presentation 0 %

Participation in Tutorials 0 %

Project work 0 %

Assignments 0 %

Reports 0 %

Research project 0 %

Quizzes 0 %

Other 0 %

Additional information:

End of year written examination: 100%

Yes/no questions- must pass with 80% or higher grade.

The student must attend/listen to all lectures.