

<u>Day 1</u>	Learning Activity	Faculty
Moderator: Isabelle Nakhla		
9:00– 9:15	Welcome, workshop's objectives, agenda setting	Nahed Moustafa, MD Suez Canal University
9:15 – 9:30	Pre-test	
9:30 –10:00	History and Principles of Research Ethics	Hany Sleem, MD Cairo University
1000 – 10:30	Criteria for Review of Research: Ethical Requirements	Nahed Moustafa, MD Suez Canal University
10:30 – 10:45	Overview of Clinical Trials	Hala Mansour, MSc National Hepatology and Tropical Medicine Research Institute
10:45 – 11:00	Discussion	
11:00 – 11:20	Distinction between research and clinical practice	Henry Silverman, MD University of Maryland, USA
11:20 – 12:00	Group Exercise: Conflicting Roles of Physician and Investigator	Faculty
12:00 – 12:30	Coffee break	
Moderator: Azza Saleh		
12:30 – 1:00	Vulnerable Subjects	Nahed Moustafa, MD Suez Canal University
1:00 – 1: 30	Group Exercise: Willowbrook Hepatitis Study	Faculty
1:30 – 2:00	GCP I: Introduction to Good Clinical Practice	Isabelle Nakhla, MD Navy Medical Research Unit - 3
2:00 – 2:30	GCP II: Investigator's responsibilities*	Mohamed Adel, MBBCH
2:30 – 2:45	Discussion	
2:45 – 3:00	Evaluation form of day (1)	

<u>Day 2</u>	Learning Activity	Faculty
Moderator: Nahed Moustafa		
9:00 – 9:15	Sign in and Agenda setting of the second day	Nahed Moustafa, MD Suez Canal University
9:15 – 9:45	GCP III: Essential Documents	Sahar Ebrahim Quintiles Middle East
9:45 –10:15	GCP IV: Screening/Enrollment	Hala Mansour, MSc National Hepatology Tropical Medicine Research Institute
10:15 – 10:45	Informed consent/Cases	Hany Sleem, MD Cairo University
10:45 – 11:45	Group exercise: informed consent	Faculty
11:45 – 1:00	Coffee break and Al-Gomaa Pray	
Moderator: Hany Sleem		
1:00 – 1:30	GCP V: Safety in clinical trials: Adverse events and DSMB	Azza Saleh, MD Theodur Bilharz Research Institute
1:30 – 2:15	Group exercise: Adverse Events	Hala Mansour, MSc National Hepatology Tropical Medicine Research Institute
2:15 – 2:45	Issues involved in Collaborative International Research:	Isabelle Nakhla, MD Navy Medical Research Unit -3
2:45 – 3:00	Evaluation form of the second day	

<u>Day 3</u>	Learning Activity	Faculty
9:00 – 9:15	Sign-In and Agenda setting of third day	Nahed Moustafa
Moderator: Hala Mansour		
9:15 – 9:45	REC: Role and Functions/Continuing Review	Azza Saleh, MD Theodur Bilharz Research Institute
9:45 – 10:15	GCP VI: In Trial Procedures/Source Documents/Data Collection and Protocol Non-Adherence	Wesam Masoud, MD Quintiles Middle East
10:15 – 10:30	Discussion	
10:30 – 11:00	Analysis of Risks and Benefits	Nahed Moustafa, MD Suez Canal University
11:00 – 11:30	GCP VII: Principles of Quality Assurance	Radi Hammad, MBBCH
11:30 – 12:00	Coffee Break	
12:00 – 12:30	Research Misconduct	Henry Silverman, MD University of Maryland, USA
12:30 – 1:30	Group Work on Protocol	All Faculty
1:30 – 2:15	Protocol Review Discussion	All Faculty
2:15 – 2:30	Post-Test	
2:30 – 3:00	Discussion of Post Test	
3:00 – 3:30	Next Steps	
3:30 – 3:45	Hand out of certificates	