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| **FHS-logo.gif** | **Design and Analysis of Clinical Trials**  (EPHD321) | **Slide-1-(b)-concise-logo-top-right.png** |

**Coordinator/Instructor Details:**  
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Other instructors:** Ghada El-Hajj Fuleihan, MD, MPH. email: **gf01@aub.edu.lb**

**Course Information:**  
Credits: 2   
Class Time:  Wednesdays (2 hours) 1:30 pm- 3:30 pm and 2 Fridays and Saturdays (4 hours) 3:30-5:00 (Friday) and 9:00am to 1:00pm (Saturday) as per Schedule below.  
Course location: live online and face to face

**Course Description:**   
A course that focuses on issues in the design and analysis of randomized controlled clinical trials: Phases, patient selection, recruitment, masking and randomization, endpoint definition, different designs and corresponding statistical analysis.

**Course Objectives:**

1. To understand basic principles of clinical trial design including bias, randomization, blocking, masking, ...etc
2. To be familiar with statistical concepts that will be used in the analysis and interpretations of trial outcomes
3. To demonstrate the knowledge of methods used in the analysis of specific designs like factorial designs, cross over designs...etc

**Course structure**

In addition to PowerPoint presentations in class, supportive reading material will be made available online when needed. Some of those reading materials will be accompanied with homework to be submitted on a specific date. All lectures, reading materials and exercises will be posted on moodle.

**Tentative Grading:**             
Your grade will be based on the following

**Activity percentage Objectives**

Home Works 20% 1,2

Midterm 35% 1,3

Final 45% 1,2,3

**Academic Integrity/Dishonesty:** Cheating and plagiarism will not be tolerated. Review the Student Code of Conduct in your handbook and familiarize yourself with definitions and penalties. If you’re in doubt about what constitutes plagiarism, ask your instructor because it is *your* responsibility to know. The American University of Beirut has a strict anti-cheating policy. Penalties include failing marks on the assignment in question, suspension or expulsion from the University and a permanent mention of the disciplinary action in the student’s records.

**Students with Disabilities:**

Staff members of the AUB Office of Student Affairs, Room 113, West Hall, coordinate accommodations and services for students with special needs. If you have a disability, for which you may request accommodation in AUB classes, consult the website for more information and arrange with the Coordinator (<https://www.aub.edu.lb/SAO/Pages/Accessible-Education.aspx>). Also, please see the instructor of this course privately about possible support services that can be provided to you.

**Non-Discrimination-Title IX-AUB:**

AUB is committed to facilitating a campus free of all forms of discrimination including sex/gender-based harassment prohibited by Title IX. The University’s non-discrimination policy applies to, and protects, all students, faculty, and staff. If you think you have experienced discrimination or harassment, including sexual misconduct, we encourage you to tell someone promptly. If you speak to a faculty or staff member about an issue such as harassment, sexual violence, or discrimination, the information will be kept as private as possible, however, faculty and designated staff are required to bring it to the attention of the University’s Title IX Coordinator. Faculty can refer you to fully confidential resources, and you can find information and contacts at[www.aub.edu.lb/titleix](https://www.aub.edu.lb/titleix). **To report an incident**, contact the University's Title IX Coordinator Trudi Hodges at 01-350000 ext. 2514, or [titleix@aub.edu.lb](mailto:titleix@aub.edu.lb). An anonymousreportmay be submittedonline via EthicsPoint at [www.aub.ethicspoint.com](https://www.aub.ethicspoint.com/).

**COPYRIGHT NOTICE:**   
Students are allowed to make one single copy of the course material for personal use during the semester. Copies of course material for third parties are forbidden. Students will be responsible for any misuse of material of this course

**Tentative Schedule**

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| **Date** | **Lecture title** | **Instructor** |
| WED 30 - Aug | Introduction to Clinical Trials | Dr El Hajj Fuleihan |
| WED 06 - Sep | Phase 1 Clinical Trials | Dr Mahfoud |
| WED 13 - Sep | Phase 2 Clinical Trials | Dr Mahfoud |
| FRI/SAT  22/23 Sept | Phase 3 Clinical Trials - 1 | Dr Mahfoud |
| Phase 3 Clinical Trials -2 (randomization, power, effect size and sample size) | Dr Mahfoud |
| Phase 3 Clinical Trials - 3 (data analysis and practice) | Dr Mahfoud |
| WED 04-Oct | Factorial Designs |  |
| WED 11-Oct | Midterm | Dr Mahfoud |
| WED 18-Oct | Cross-over Design | Dr Mahfoud |
| WED 25-Oct | Cluster Randomized Clinical Trials | Dr Mahfoud |
| FRI/SAT  03/04 NOV | Applications, critical evaluation of clinical trials, and stopping rules of clinical trials | Dr Mahfoud |
| WED 08-Nov | Non-inferiority and Adaptive Designs | Dr Mahfoud |
| WED 15-Nov | Special topics in Clinical trials | Dr Mahfoud |
| WED 29-Nov | Practical issue in Clinical Trials | Dr El Hajj Fuleihan |
| TBD | Final Exam |  |