BSTA 661: DESIGN OF INTERVENTIONAL STUDIES  
INSTRUCTOR: ALISA J. STEPHENS-SHIELDS, PHD, FALL SEMESTER 2022  
MONDAYS AND WEDNESDAYS, 12:00-1:30 PM, BLOCKLEY 418

SYLLABUS:

Description: This course is designed for graduate students in statistics or biostatistics interested in the issues underlying the design of interventional studies. General topics include designs for various types of clinical trials (Phase I, II, III), endpoints and control groups, statistical inference in interventional studies, sample size determination, and design considerations for adaptive designs and interventions. Regulatory and ethical issues will also be covered. Students should have a working knowledge of basic biostatistical principles and familiarity with a statistical programming language (e.g. R, SAS). (0.5 course unit, second half of fall semester)

Prerequisites: Permission of instructor


Supplementary Texts: See next page (optional, students may find helpful for additional reading)

Grading: There will be three homework assignments and a final project. Grading will be based on the homework (75%), and class participation (25%).

Teaching Assistant: Melanie Loth

Labs: There will be 3 optional labs after each homework is assigned. The location, time, and format (virtual or in person) is to be determined.

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<td>Lecture 1</td>
<td>Introduction to Interventional Studies</td>
<td>6.1-6.3,3.1-3.4</td>
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<td>September 7</td>
<td>Lecture 2</td>
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<td>October 17</td>
<td>Lecture 13</td>
<td>SMARTs for Adaptive Interventions</td>
<td>Almirall et al. (2011)</td>
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Texts Recommended for Further Reading on Clinical Trials

Highly-recommended:

Other Texts on Clinical Trials in General:

Specialized Trial Designs:

Sequential/Adaptive Methods and Monitoring:

Related Topics: