DEPARTMENT OF BIOSTATISTICS
UNIVERSITY of WASHINGTON
School of Public Health

BIOST/STAT 524: Design of Medical Studies

Quarter: Spring 2018
Time and Location: MW 8:30-9:50am, Health Sciences T473
Grading: 3 credits, graded
Instructor: Thomas Fleming, Department of Biostatistics (tfleming@uw.edu)
Prerequisites: BIOST 511 or equivalent, and one of BIOST 513, BIOST 518, STAT 421, STAT 423, STAT 512, or EPI 512; or permission of instructor
SLN: 11489 (BIOST 524) or 19675 (STAT 524)

Design of medical studies, with emphasis on randomized controlled clinical trials.

We will explore many challenging and often controversial issues: eliminating bias, need for randomization, intention to treat principles, reducing variation, addressing missing data, phases of clinical research, role of Phase 2b screening trials, identifying and addressing safety signals, conducting confirmatory studies, when to use blinding, computing power and sample sizes, factorial designs, choosing proper endpoints, role of surrogate markers, designing non-inferiority trials, group sequential guidelines, the importance of confidentiality of interim results, role of data monitoring committees, adherence and retention requirements, interpreting confirmatory and exploratory analyses, and ethical issues in clinical research.

These issues will be carefully examined, with extensive reliance on examples from clinical areas such as HIV/AIDS, oncology and cardiovascular diseases. Suitable for physicians, graduate students in biostatistics, epidemiology, medicine, and other related scientific fields.