COURSE AND CONTACT INFORMATION

Course: Statistics course STAT 6289, Section 13 (Clinical Trials)
Semester: Spring 2015 (January 12-May 12)
Class: Time: Tuesdays 6:10-8:40 pm
Location: 2020 K Street, Room 12

INSTRUCTOR
Name: Professor Michael Proschan
Campus Address: Rome Hall 676
E-mail: Proschan@gwu.edu
Office hours: After class (Tuesdays 8:45-9:45 just outside classroom) or by appointment

COURSE DESCRIPTION
This course uses a wealth of case studies to cover the fundamentals of clinical trials, including design, analysis, and interim monitoring

COURSE PREREQUISITE(S):


LEARNING OUTCOMES:
As a result of completing this course, you will be able to:
1. Understand how randomization sets clinical trials apart from every other type of study and why clinical trials are considered the gold standard of medical evidence
2. Design a clinical trial or critique the design of a clinical trial
3. Understand statistical methodology used in clinical trials, including statistical methods of monitoring clinical trials

GRADING
30% Homework
30% Midterm
40% Final

Tentative Schedule

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<td>Randomization-Based Inference</td>
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<td>Meta-Analysis</td>
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<td>15</td>
<td>4/21</td>
<td>A Trial in my Son</td>
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**Homework:** due 1 week after assigned

**Midterm:** A midterm examination will be given on 2/24. 2 pages of notes are allowed.

**Holiday:** 3/10 there is no class.

**Final Exam:** The final exam is cumulative. 2 pages of notes are allowed.

**Incomplete:** will only be considered when 1) you are passing the course AND 2) you cannot complete the course because of illness or other circumstances beyond your control.

**CLASS POLICIES**

**Attendance policy:**
You are expected to attend every lecture. You are responsible for the material covered and the handouts distributed during lecture.

**Late work:** will not be accepted.

**Make-up exams:** Makeup examinations will only be given in exceptional circumstances (e.g. well documented medical emergency).

**ACADEMIC INTEGRITY**
I personally support the GW Code of Academic Integrity. It states: “Academic dishonesty is defined as cheating of any kind, including misrepresenting one’s own work, taking credit for the work of others without crediting them and without appropriate authorization, and the fabrication of information.” For the remainder of the code, see: [http://www.gwu.edu/~ntegrity/code.html](http://www.gwu.edu/~ntegrity/code.html)

**SUPPORT FOR STUDENTS OUTSIDE THE CLASSROOM**

**DISABILITY SUPPORT SERVICES (DSS)**
Any student who may need an accommodation based on the potential impact of a disability should contact the Disability Support Services office at 202-994-8250 in the Marvin Center, Suite 242, to establish eligibility and to coordinate reasonable accommodations. For additional information please refer to: [http://gwired.gwu.edu/dss/](http://gwired.gwu.edu/dss/)

**UNIVERSITY COUNSELING CENTER (UCC) 202-994-5300**
The University Counseling Center (UCC) offers 24/7 assistance and referral to address students' personal, social, career, and study skills problems. Services for students include: crisis and emergency mental health consultations, confidential assessment, counseling services (individual and small group), and referrals [http://gwired.gwu.edu/counsel/CounselingServices/AcademicSupportServices](http://gwired.gwu.edu/counsel/CounselingServices/AcademicSupportServices)

**SECURITY:** In the case of an emergency, if at all possible, the class should shelter in place. If the building that the class is in is affected, follow the evacuation procedures for the building. After evacuation, seek shelter at a predetermined rendezvous location.

**Exams**

Exams are closed book and notes. **You may have two pages of summary for the exams. Each page may have a front and back.**

**Blackboard**
Check it frequently. I will upload many, but not all, handouts, examples, project descriptions, etc on BB.