Course: STAT6289, Clinical Trials
Semester: Fall 2016
Time: Tuesday 6:10-8:40, 08/29/2016-12/12/2016
Location: FNGR 223
Instructor: Aiyi Liu
Campus Address: Rome Hall, 801 22nd Street, NW
Phone: (571) 345-4534
E-mail: aiviliu@gwu.edu or aiviliu65@gmail.com
Class time: Tuesday 6:10-8:40
Office Hours: Tuesday 8:40-9:10

Course Description:

This is primarily a lecture course designed to introduce you to the design and analysis of clinical trials, one of the most important area in medical research that statisticians are actively and intensively involved. Major topics to be covered are

- Clinical Trials as a Tool for Medical Research
- Different Phases of Clinical Trials
- Various Designs of Clinical Trials
- Endpoints in Clinical Trials
- The Role of Randomization
- Power and Sample Sizes in Clinical Trial
- Statistical Analysis of Clinical Trial Data
- Interim Analysis and Monitoring

Learning Outcomes:

As a result of completing this course, you will be able to:

1. Understand a statistician’s role in a clinical trial.
2. Understand the aims of different phases of a clinical trial.
3. Compute the sample size and power requirement for designing a trial
4. Analyze clinical trial data and interpret the analysis results
5. Conduct interim analysis and data monitoring

Assessment Procedures and Final Grade:

Students will take notes, work on homework problems, and take a midterm and a final exam. Make-up exams will not be given unless there is a medical emergency. Final grade will be based on a score, ranging from 0 to 100 maximum, computed by weighting homework (50%), midterm (25%) and the final exam (25%).
There will be about 6-8 homework sets, involving working on a statistical problem related to clinical trial, or writing a summary after reading selected clinical trial materials. All graded work will usually be returned and discussed one week after due date. Unless otherwise instructed, students are expected to work independently on each problem set.

Regular attendance is expected although it is not included in the final grade.

**Textbooks and Readings**

**Required:**

**Recommended:**

**Prerequisite:** Statistics courses that cover continuous and normal distributions, binomial distributions, estimation, hypothesis testing, two-sample t-test, and regression analysis.

R and SAS programming language will be used and the computational aspects will include computing moments and quantiles of a distribution. The R software is free and can be downloaded from http://www.r-project.org/. You are expected to be familiar with the R and SAS software. GW labs provide access to SAS and have a site license for SAS. To obtain a copy for your PC contact the Advanced Technology Lab in the basement of Gelman library. See [http://citl.gwu.edu/pages/sas.html](http://citl.gwu.edu/pages/sas.html)

**Table 1. Classroom Schedule and Activities**

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<thead>
<tr>
<th>Week</th>
<th>Topics for Class Lectures and Activities</th>
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<tbody>
<tr>
<td>1</td>
<td>An overview of design and analysis of clinical trials and the role of biostatisticians</td>
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<tr>
<td>2</td>
<td>Dose finding and phase I trials</td>
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<td>3</td>
<td>Design and analysis of phase II trials</td>
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<td>4</td>
<td>Phase III clinical trials</td>
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<td>5</td>
<td>Power analysis and sample size calculation: Binary and continuous outcomes</td>
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<tr>
<td>6</td>
<td>Power analysis and sample size calculation: Longitudinal and time-to-event outcomes</td>
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<td>7</td>
<td>Cross-over designs</td>
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<td>8</td>
<td>Randomization</td>
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<td>9</td>
<td>Clinical trials analysis: p-values</td>
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<td>10</td>
<td>Clinical trials analysis: baseline summary and test for treatment effects</td>
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<tr>
<td>11</td>
<td>Clinical trials analysis: time-to-event data</td>
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<td>12</td>
<td>Clinical trials analysis: longitudinal data</td>
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<td>13</td>
<td>Interim analysis and data monitoring</td>
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<td>14</td>
<td>Robust procedures in clinical trials data analysis</td>
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**Class Policies**

Late submissions of homework solutions and make-up of missed exams will be accepted only under rare conditions as laid out in the University Policy on Religious Holidays, or health conditions with a written proof from a medical doctor.

**University Policy on Religious Holidays:**

1. Students should notify faculty during the first week of the semester of their intention to be absent from class on their day(s) of religious observance;
2. Faculty should extend to these students the courtesy of absence without penalty on such occasions, including permission to make up examinations;
3. Faculty who intend to observe a religious holiday should arrange at the beginning of the semester to reschedule missed classes or to make other provisions for their course-related activities

[NOTE: for other university policies on teaching, see http://www.gwu.edu/~academic/Teaching/main.htm ]

**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

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/

**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

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.