Mel and Enid Zuckerman College of Public Health  
University of Arizona

SYLLABUS  
CPH 675: Clinical Trials and Intervention Studies  
SPRING 2015

Time:  Tuesdays, 3:00-5:50 PM

Location:  Drachman Hall, A120

Instructor:  Dr Melanie Bell, Drachman A240, 1295 Martin Ave, Tucson AZ 85724, 626-2795  
MelanieBell@email.arizona.edu

Office Hours:  By appointment

Catalog Description:  A fundamentals course on issues in the design, operation and analysis of controlled clinical trials and intervention studies. Emphasis on randomized long-term multicenter trials.

Course Prerequisites:  CPH 576A, CPH 576B (can be taken concurrently).

Course Learning Objectives:  The objective of this course is to provide a foundation in the design, conduct, analysis and reporting of randomized trials and intervention studies.

Program Competencies Covered:

PhD biostatistics:
- Be able to describe the roles biostatistics serves in the discipline of public health;
- Apply basic informatics techniques and vital statistics and public health records in the description of public health characteristics and in public health research and evaluation;
- Communicate understanding of the assumptions necessary for a given statistical procedure as well as the ability to determine if the assumptions are met for a given dataset;
- Demonstrate the ability of communicate effectively in writing reports, giving oral presentations, and teaching basic statistic material in a formal classroom setting;
- Be capable of assuming positions of leadership in a career in academia, research, institutes, government, and/or industry.

MS biostatistics:
- Ability to identify appropriate statistical tools to address specific scientific questions;
- Ability to select appropriate research designs to meet the needs of various studies, and be able to explain the limitations of implemented designs;
- Ability to skillfully engage in statistical collaboration with mentors, colleagues, and clients;
- Demonstrate excellent presentation skills and the ability to explain statistical concepts and findings to a general scientific audience.
MPH biostatistics;
- All of the competencies for the MS in biostatistics, plus;
- Demonstrate understanding of methods of data analysis and data monitoring.

**Recommended Texts/Readings:**
- Other journal articles and websites, as shown below

**Website resources:**
- National Institutes of Health: www.clinicaltrials.gov
- Food and Drug Administration: www.fda.gov
- CONSORT Statement: http://www.consort-statement.org/
- The Cochrane Collaboration: www.cochrane.org
- International Committee on Harmonisation: www.ich.org

**Course Requirements:** Attendance at lectures, participation in discussions, completing assigned readings including reading papers in preparation for quizzes, group work, and completion of assignments.

**Statistical Software:**
You will be required to use a statistical software package for this class. You may use SAS, Stata, R or SPSS. I will **not** be giving software support. However, I am familiar with each of the packages, with my expertise following the order they are listed.

**A few notes on email & technology:**
I often do not check email evenings and weekends. Please do not expect instant communication with me. Please make appointments with me by email, and reply to confirm a time. Use of laptop, phone or tablet during lecture or guest presentations for anything other than note-taking is disrespectful and will result in a loss of attendance points for the day.

**Grading/Student Evaluation:**
- Weekly quizzes (20%). These will be a short quiz due before each class, mostly on the readings. The lowest two of these will be dropped.
- Individual homework (45%). There will be four homework assignments throughout the semester. Each day late will result in a 10% decrease in grade.
- Attendance and participation (5%). The lowest of these will be dropped.
- Research protocol (30%). Groups of 2-4 students will write a research protocol for an intervention study. At the end of the semester each group will give a 20 minute presentation on their study.

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<tr>
<th>Your final grade will be determined as follows:</th>
<th>Letter grades will be assigned as follows:</th>
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<tr>
<td>Weekly quizzes 20%</td>
<td>Letter grade</td>
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<tr>
<td>Individual homework 45%</td>
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<td>Attendance &amp; participation 5%</td>
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<td>Protocol 30%</td>
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There will be no opportunity for extra credit.
**Tentative Course Schedule.** Updated schedules to be posted on D2L. ICH=International Conference on Harmonisation ICH_E9 (numbers refer to pages to read); Ch refers to chapter of the Friedman et al textbook; GCP=Good Clinical Practice (ICH_E6)

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<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Guest lecturer/topic</th>
<th>Reading</th>
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<tr>
<td>Feb 3</td>
<td><strong>Randomization</strong>&lt;br&gt;Simple&lt;br&gt;Blocked&lt;br&gt;Stratified&lt;br&gt;Minimization</td>
<td>Robin Harris</td>
<td>Ch6&lt;br&gt;ICH p9-11&lt;br&gt;Scott, NW, et al (2002). The method of minimization for allocation to clinical trials. a review. Controlled Clinical Trials, 23(6), 662-674.</td>
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<td>Feb 10</td>
<td><strong>Experimental design</strong>&lt;br&gt;Parallel group&lt;br&gt;Crossover&lt;br&gt;Factorial&lt;br&gt;Non-inferiority&lt;br&gt;Cluster</td>
<td>Cyndi Thompson/ Methodological issues diet &amp; exercise</td>
<td>Ch5&lt;br&gt;ICH p11-18&lt;br&gt;TGN1412 paper</td>
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<td>Feb 17</td>
<td><strong>Analysis of phase III trials</strong></td>
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<td>Ch 9 &amp; 17&lt;br&gt;ICH p24-29</td>
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<td>Date</td>
<td>Topic</td>
<td>Speaker/Resource</td>
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<td>Mar 17</td>
<td>SPRING BREAK</td>
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<td>Date</td>
<td>Title</td>
<td>Presenter/Details</td>
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<td>Apr 21</td>
<td>Monitoring</td>
<td>Group sequential methods/Interim analysis Adverse events Chris Bime/multicenter</td>
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<td>trials, practical issues Ch12, 16</td>
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<td>issues and controversies regarding confidentiality. Statistics in Medicine, 21(19),</td>
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<td>2843-285</td>
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<td>Hammer SM et al. (2013) Efficacy trial of a DNA/rAd5 HIV-1 preventive vaccine.</td>
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<td>N Engl J Med</td>
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<td>Apr 28</td>
<td>Phase I &amp; II Pilot studies</td>
<td>Non-inferiority ICH p14-16</td>
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<td>and Clinical Pharmacology, 17(4), 483-490.</td>
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<td>BMC Medical Research Methodology, 10, 1.</td>
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<td>Merchant et al. (2012) Phase I Trial and Pharmacokinetic Study of Lexatumumab in</td>
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<td>Pediatric Patients With Solid Tumor.</td>
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<td>May 5</td>
<td>Presentations</td>
<td>ICH p29-32</td>
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<td>translational research. Statistics in Medicine, 30(23), 2785-2792</td>
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**Class Attendance/Participation:**

All holidays or special events observed by organized religions will be honored for those students who show affiliation with that particular religion. Absences pre-approved by the UA Dean of Students (or Dean’s designee will be honored.)

You are expected to attend and participate in class, and are responsible for all material covered in class and in the readings. Please note that the lowest two quizzes will be dropped—this is to accommodate unavoidable absences.

**Communications:** You are responsible for reading emails sent to your UA account from your professor and the announcements that are placed on the course web site. Information about readings, news events, your grades, assignments and other course related topics will be communicated to you with these electronic methods. The official policy can be found at: [http://www.registrar.arizona.edu/emailpolicy.htm](http://www.registrar.arizona.edu/emailpolicy.htm)

**Disability Accommodation:** If you anticipate issues related to the format or requirements of this course, please meet with me. I would like us to discuss ways to ensure your full participation in the course. If you determine that formal, disability-related accommodations are necessary, it is very important that you be registered with Disability Resources (621-3268; drc.arizona.edu) and notify me of your eligibility for reasonable accommodations. We can then plan how best to coordinate your accommodations. The official policy can be found at: [http://catalog.arizona.edu/2013%2D14/policies/disability.htm](http://catalog.arizona.edu/2013%2D14/policies/disability.htm)
**Academic Integrity:** All UA students are responsible for upholding the University of Arizona Code of Academic Integrity, available through the office of the Dean of Students and online: The official policy found at: [http://deanofstudents.arizona.edu/codeofacademicintegrity](http://deanofstudents.arizona.edu/codeofacademicintegrity). Using course material from a previous semester (quizzes, homework) is a violation of academic integrity.

**Classroom Behavior:** (Statement of expected behavior and respectful exchange of ideas)
The Dean of Students has set up expected standards for student behaviors and has defined and identified what is disruptive and threatening behavior. This information is available at: [http://deanofstudents.arizona.edu/disruptiveandthreateningstudentguidelines](http://deanofstudents.arizona.edu/disruptiveandthreateningstudentguidelines)

Students are expected to be familiar with the UA Policy on Disruptive and Threatening Student Behavior in an Instructional Setting found at: [http://policy.arizona.edu/disruptive-behavior-instructional](http://policy.arizona.edu/disruptive-behavior-instructional) and the Policy on Threatening Behavior by Students found at: [http://deanofstudents.arizona.edu/sites/deanofstudents.arizona.edu/files/Disruptive_threat_bklt_2012.pdf](http://deanofstudents.arizona.edu/sites/deanofstudents.arizona.edu/files/Disruptive_threat_bklt_2012.pdf)

**Grievance Policy:** Should a student feel he or she has been treated unfairly, there are a number of resources available. With few exceptions, students should first attempt to resolve difficulties informally by bringing those concerns directly to the person responsible for the action, or with the student's graduate advisor, Assistant Dean for Student and Alumni Affairs, department head, or the immediate supervisor of the person responsible for the action. If the problem cannot be resolved informally, the student may file a formal grievance using the Graduate College Grievance Policy found at: [http://grad.arizona.edu/academics/policies/academic-policies/grievance-policy](http://grad.arizona.edu/academics/policies/academic-policies/grievance-policy)

**Grade Appeal Policy:** [http://catalog.arizona.edu/2013-14/policies/gradappeal.htm](http://catalog.arizona.edu/2013-14/policies/gradappeal.htm)

**Syllabus Changes:** Information contained in the course syllabus, other than the grade and absence policies, may be subject to change with reasonable advance notice, as deemed appropriate.

**Telephone Use:** Turn your cell phones to silent or vibrate in order to not disrupt the class and disturb your fellow students and professor.

**Plagiarism:** What counts as plagiarism?
- Copying and pasting information from a web site or another source, and then revising it so that it sounds like your original idea.
- Doing an assignment/essay/take home test with a friend and then handing in separate assignments that contain the same ideas, language, phrases, etc.
- Quoting a passage without quotation marks or citations, so that it looks like your own.
- Paraphrasing a passage without citing it, so that it looks like your own.
- Hiring another person to do your work for you, or purchasing a paper through any of the on- or off-line sources.