Georgia Southern University

Digital Commons@Georgia Southern

Public Health, Jiann-Ping Hsu College of

Spring 2015

BIOS 7231 – Clinical Trial Methodology

Karl E. Peace
Georgia Southern University, Jiann-Ping Hsu College of Public Health, kepeace@georgiasouthern.edu

Follow this and additional works at: https://digitalcommons.georgiasouthern.edu/coph-syllabi

Part of the Public Health Commons

Recommended Citation

Instructor: Karl E. Peace
Office: Hendrix Hall #1005
Phone: 912-478-7905
E-Mail Address: kepeace@georgiasouthern.edu or peacekarl@frontier.com
Office Hours: Wednesday – 3:00 PM – 5:00 PM
                    And – By appointment, any time via email
Web Page: http://www.georgiasouthern.edu/~kepeace/
Class Meets: Wednesday – 5:00 PM-to-7:30 PM via electronic classroom 2 weeks of each
                    Month and onsite 2 weeks of each month.

-- **Course schedules can be found at:** http://www.collegesource.org/displayinfo/catalink.asp --

Prerequisites: BIOS 6541; BIOS 7534

VISTA Address: **Via MyGeorgiaSouthern on GSU Home Page**

Catalog Description: Students are introduced to regulatory, scientific, statistical and
                          practical aspects of methods inherent in design, monitoring and
                          analysis of clinical trials. Clinical trials in many areas of drug
                          development are presented, discussed and critiqued.

Required Textbook: Clinical Trial Methodology by Karl E. Peace and Din Chen
                          Series: Chapman & Hall/CRC Biostatistics Series
                          Cat. #: C9179
                          ISBN: 9781584889175
                          ISBN 10: 1584889179
                          Publication Date: July 19, 2010
                          Number of Pages: 420

                          The course is presented using power points. Students are
                          provided copies of the power points on a Flash Drive.

Secondary Texts:

Chen D, Peace KE (2010): Clinical Trial Data Analysis using R; Chapman & Hall/CRC, Taylor and Francis Group; ISBN: 978-1-4398-4020-7

Chen, D, Peace KE: Applied Meta-Analysis using R. Chapman & Hall/CRC, Taylor and Francis Group; 13: 978-1-4665-0599-5; May, 2013.

Chen D, Sun J, Peace KE [Editors and Author contributors] (2012): Interval-Censored Time-to-Event Data: Methods and Applications"; Chapman & Hall/CRC, Taylor and Francis Group; Published July, 2012.

Peace, K. E. [Editor and Author contributor] (2008): Design and Analysis of Clinical Trials with Time to Event Endpoints; Chapman & Hall/CRC Taylor and Francis Group; Boca, ISBN 978-1-4200-6639-5.

Peace, K. E. [Editor and Author contributor] (1992): Biopharmaceutical Sequential Statistical Applications. Marcel Dekker, Inc., New York, ISBN 0-8247-8628-9.

Peace, K. E. [Editor and Author contributor] (1990): Statistical Issues in Pharmaceutical Drug Development. Marcel Dekker, Inc., New York, ISBN 0-8247-8290-9.

Peace, K.E. [Editor and author] (1988): Biopharmaceutical Statistics in Drug Development. Marcel Dekker, Inc., New York, ISBN 0-8247-7798-0.

M.P.H. Biostatistics Concentration Competencies:

Upon graduation a student with an M.P.H. in Biostatistics should be able to:

1. Construct a public health and biomedical research question from ideas, conditions, and events that exist in a rural and urban community, region, state, and nation using critical thinking skills;

2. Identify objectives of a public health and biomedical research question;

3. Express objectives in the appropriate biostatistical framework such as hypothesis testing, estimation, and prediction;

4. Evaluate objectives of a public health research question to ensure the appropriate type of data is collected for analysis;

5. Design an experiment or survey pertaining to a public health and biomedical research question in order to collect the data needed to meet objectives of public health research;

6. Apply appropriate statistical tools and software in order to analyze data;

7. Demonstrate use of Statistical Analysis Software (SAS) to input, manage, merge, export, and conduct analysis on public health and biomedical data;

8. Analyze data using appropriate categorical analysis techniques to obtain valid and reliable results;

9. Analyze quantitative data using appropriate biostatistical methods such as simple and multiple regression and clinical trial methodology;

10. Provide statistical requisites for developing a protocol for conducting a clinical trial;

11. Describe key concepts and theory underlying biostatistical methodology used in probability and inferential, analytical, and descriptive statistics;

12. Interpret results of biostatistical analyses so that valid and reliable conclusions regarding a public health and biomedical research question may be drawn from the analyses;

13. Develop written and oral reports to communicate effectively to research investigators pivotal aspects of a study, including its design, objectives, data, analysis methods, results, and conclusions;

14. Create a collaborative environment for working on written and oral reports and developing critical thinking skills.

Course Objectives: At the end of this course, students will be able to:

1. Translate public health and biomedical research objectives into statistical hypotheses (competencies 1, 2, 3, 4)

2. Design public health and biomedical research clinical trials (competencies 1, 2, 3, 4, 5)

3. Develop Statistical Analysis Sections for pubic health and biomedical research Protocols (competencies 1, 2, 3, 4, 5, 8, 9, 10)

4. Explain the requirements for good protocol development for public health and biomedical research clinical trials (competencies 1, 2, 3, 4, 5, 8, 9, 10, 13, 14)

5. Apply common statistical descriptive and inferential analysis methods to data collected in public health and biomedical research clinical trials (competencies 6, 7, 8, 9)

6. Describe methodological alternatives to commonly used statistical methods used in public health and biomedical research clinical trials when analysis assumptions are not met (competencies 6, 7, 8, 9)

7. Interpret results of statistical analyses of data collected from public health and biomedical clinical trials (competency 12)

8. Develop written and oral presentations based on statistical analyses of public health and biomedical research clinical trials, for both public health professionals and educated lay audiences (competencies 12, 13, 14)

9. Identify key federal regulation 'governing' the conduct of clinical trials (competency 10)

10. Explain the importance of the numbers of patients in clinical trials (competency 11)

11. Explain the importance of monitoring adverse experiences in clinical trials (competencies 2, 5, 6 ,10)

12. Describe methods for monitoring adverse experiences in clinical trials (competencies 2, 5, 6, 10)

13. Explain how data from multicentre clinical trials may be 'pooled' (competencies 6, 7, 8, 9, 10, 13)

14. Describe the issues in group sequential clinical trials (competencies 11, 12, 13)

Instructional Methods: Class meetings will be a combination of lecture and class discussion. Approximately half of the class meetings will be facilitated via Adobe Connect in real time (blended format) and the remainder physically in the classroom. Homework assignments, class participation and the final examination constitute the basis of student evaluation.   Students are expected to make use of office hours and email contact to discuss concepts or difficulties they may have. In addition, they may seek the assistance of the GA.

Daily Study Log: Students are required to keep a daily computerized study log. The study log should have a column for the date, a column to identify topic of study, a column to identify the time of beginning study, a column to identify the ending time of study, and a column to identify the amount of time spent in studying the topic.

Final Examination: May ??　　　Last day of classes
　　　　　　　　　　　May ??　　　Final exams

　　　Grading: Weighting of assignments for purposes of grading will be as follows:

　　　　　　　　Final Exam (objectives 1-14, integrated)……………60%
　　　　　　　　Assignment (objectives 1-14, individually)………..30%
　　　　　　　　Class Participation (objectives 1-14, individually)…10%
　　　　　　　　　　　　　　　　　　　　　　　　　　　　＿＿＿
　　　　　　　　Total Possible　　　　　　　　　　　　　　100%

The following point scale will be utilized in grading:

90% - 100%	A
80% - 90%	B
70% - 80%	C
60% - 70%	D

There are times when extraordinary circumstances occur (e.g., serious illness, death in the family, etc.). In such circumstances, and/or if you need additional time to satisfactorily complete any course requirement, please consult with the instructor within a reasonable amount of time.

Academic Misconduct: As a student registered at this University, it is expected that you will adhere to only the strictest standards of conduct. It is recommended that you review the latest edition of the *Student Conduct Code* book, as well as the latest *Undergraduate & Graduate Catalog* to familiarize yourself with the University's policies in this regard. Your continued enrollment in this course is an implied contract between you and the instructor on this issue; from this point forward, it is assumed that you will conduct yourself appropriately.

Academic integrity relates to the appropriate use of intellectual property. The syllabus, lecture notes, and all materials presented and/or distributed during this course are protected by copyright law. Students are authorized to take notes in class, but that authorization extends only to making one set of notes for personal (and no other) use. As such, students are not authorized to sell, license, commercially publish, distribute, transmit, display, or record notes in or from class without the express written permission of the instructor.

Academic Handbook: Students are expected to abide by the Academic Handbook, located at http://students.georgiasouthern.edu/sta/guide/. Your failure to comply with any part of this Handbook may be a violation and thus, you may receive an F in the course and/or be referred for disciplinary action.

**University Calendar
for the Semester:** The University Calendar is located with the semester schedule, and can be found at:
http://students.georgiasouthern.edu/registrar/calendar.htm

Attendance Policy: Federal regulations require attendance be verified prior to distribution of financial aid allotments. Attendance will not be recorded after this initial period.

One Final Note: The contents of this syllabus are as complete and accurate as possible. The instructor reserves the right to make any changes necessary to the syllabus and course material. The instructor will make every effort to inform students of changes as they occur. It is the responsibility of the student to know what changes have been made in order to successfully complete the requirements of the course.

Overview of the Content to be Covered During the Semester:

Module I: An Overview of the Regulation of Pharmaceuticals

Module II: An Overview of the Processes of Discovery, Basic Research, Clinical Development and Manufacturing in Pharmaceutical Development

Module III: Biostatistical Aspects of Clinical Drug Development
  A. The Components of a Protocol
  B. Statistical Analysis Section of a Clinical Trial Protocol

Module IV: Bioavailability & Bioequivalence of Pharmaceutical Formulations

Module V: The Design and Analysis of Pivotal Clinical Trials to Assess the Efficacy of Drugs to Treat Panic Disorder

Module VI: Clinical Trials in the Prevention of NSAID Induced Gastric Ulceration

Module VII: Biostatistical Aspects of the Development of H2-Receptor Antagonist Drugs in the Treatment of Duodenal Ulcers

Module VIII: Biostatistical Aspects of the Development of Antianginal Drugs

Module IX: Biostatistical Aspects of the Development of Drugs to Treat Alzheimer's disease Based upon Enrichment Designs

Module X: The Importance of Numbers (of Patients) in Cancer Clinical Trials

Module XI: Biostatistical Aspects of the Design of Cancer Trials

Module XII: Biostatistical Aspects of the Analysis and Interpretation of Cancer Clinical Trials

Module XIII: Monitoring Adverse Experiences in Clinical Drug Development

Module XIV: The Pooling of Data from Multicenter Clinical Trials

Module XV: Interim Analyses: p-Value and Power Computations in Multiple Look Trials

Module XVI: Statistical Analysis of Dose Response Trials

Student Information (CTM Class):

Print Full Name	email address	Pledge to spend enough time to master material? Circle one.		
1. _____	_____	Yes	No	Undecided
2. _____	_____	Yes	No	Undecided
3. _____	_____	Yes	No	Undecided
4. _____	_____	Yes	No	Undecided
5. _____	_____	Yes	No	Undecided
6. _____	_____	Yes	No	Undecided
7. _____	_____	Yes	No	Undecided
8. _____	_____	Yes	No	Undecided
9. _____	_____	Yes	No	Undecided
10. _____	_____	Yes	No	Undecided
11. _____	_____	Yes	No	Undecided
12. _____	_____	Yes	No	Undecided