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BIOS 7231 – Clinical Trial Methodology

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Georgia Southern University
Jiann-Ping Hsu College of Public Health

BIOS 7231 – Clinical Trial Methodology
Spring 2018

<u>Instructor:</u>	Karl E. Peace
<u>Office:</u>	Hendrix Hall #1005
<u>Phone:</u>	912-478-7905
<u>E-Mail Address:</u>	kepeace@georgiasouthern.edu or peacekarl@frontier.com
<u>Office Hours:</u>	Wednesday – 3:00 PM – 5:00 PM And – By appointment, any time via email & WebEx Software
<u>Web Page:</u>	http://www.georgiasouthern.edu/~kepeace/
<u>Class Meets:</u>	Wednesday – 5:00 PM-to-7:45 PM via combination of in class lectures and electronic virtual classroom lectures via WebEx Software

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

Prerequisites: BIOS 6541; BIOS 7534; or by permission of instructor

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 (2017): Clinical Trial Data Analysis using R and SAS; Chapman & Hall/CRC, Taylor and Francis Group; ISBN: 978-1-4987-7982-4

- 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 (2013): 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 contributor] (1988): Biopharmaceutical Statistics in Drug Development. Marcel Dekker, Inc., New York, ISBN 0-8247-7798-0.

Biostatistics Student Learning Outcomes (BSLO):

Cross-cutting:

1. Demonstrate proficiency and effectiveness in the communication of core public health principles and practices, both oral and written.
2. Demonstrate proficiency in the integration of the core public health disciplines (Biostatistics, Epidemiology, Environmental Health, Health Policy/Management, and Social/Behavioral Science) in practice and research.
3. Demonstrate proficiency in problem solving, critical thinking, and public health leadership.

MPH Biostatistics Concentration:

1. Provide the biostatistical components of the design of a public health or biomedical experiment by: clarifying the research objectives or questions; determining data and endpoints to be collected appropriate for the objectives; translating the objectives into biostatistical questions via hypothesis testing or confidence interval frameworks; determining the appropriate sample size; and writing the statistical analysis section of the experiment.
2. Apply appropriate statistical analysis methods using SAS to analyze both categorical and quantitative data.
3. 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 ensuring that results and conclusions are valid and reliable and address the research objectives.
4. Create a collaborative environment for working on written and oral reports and developing critical thinking skills.

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

Course Objectives:

1. Translate public health and biomedical research objectives into statistical hypotheses (BSLO 1, 3, 4, 5)
2. Design public health and biomedical research clinical trials (BSLO 1, 3, 4, 5)
3. Develop Statistical Analysis Sections for public health and biomedical research Protocols (BSLO 1, 2, 3, 4, 5)
4. Explain the requirements for good protocol development for public health and biomedical research clinical trials (BSLO 1, 2, 3, 4, 5)
5. Apply common statistical descriptive and inferential analysis methods to data collected in public health and biomedical research clinical trials (BSLO 1, 2, 3, 4, 5)
6. Describe methodological alternatives to commonly used statistical methods used in public health and biomedical research clinical trials when analysis assumptions are not met (BSLO 2, 3, 5)
7. Interpret results of statistical analyses of data collected from public health and biomedical clinical trials (BSLO 1, 2, 3, 4, 5)
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 (BSLO 1, 2, 3, 4, 5)
9. Identify key federal regulation ‘governing’ the conduct of clinical trials (BSLO 1, 3, 5)
10. Explain the importance of the numbers of patients in clinical trials (BSLO 1, 2, 3, 4, 5)
11. Explain the importance of monitoring adverse experiences in clinical trials (BSLO 1, 2, 3, 5)
12. Describe methods for monitoring adverse experiences in clinical trials (BSLO 1, 2, 3, 5)
13. Explain how data from multicentre clinical trials may be ‘pooled’ (BSLO 1, 2, 3, 5)
14. Describe the issues in group sequential clinical trials (BSLO 1, 2, 3, 5)

Instructional Methods: Class meetings will be a combination of lecture and class discussion in a blended format (In classroom, and virtual classroom via WebES in real time). Lectures for classes conducted via WebEX will be recorded so that students can replay them as a way of review. After each class, students are expected to send to Dr. Peace 1 – 2 questions about material covered in the class. The questions and their answers will be compiled into a Word document and sent to students before the next class. The questions and their answers will be discussed by Dr. Peace at the beginning of the next class. Homework assignments, class participation and the final examination constitute the basis of student grades. Students are expected to make use of office hours (in office or via WebEX) 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: April 27, 2018 Last day of classes

April 30- May 04, 2018 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	<u>100%</u>

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/conduct/>. 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: The University Calendar for the semester 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. **Students are expected to attend each class meeting.**

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: Interim Analyses: p-Value and Power Computations in Group Sequential Trials

Module VI: Design & Analysis of Pivotal Clinical Trials to Assess the Efficacy of Drugs to Treat Panic Disorder

Module VII: Design & Clinical Trials in the Prevention of NSAID Induced Gastric Ulceration

Module VIII: Design & Analysis of Clinical Trials in the development of H₂-Receptor Antagonist Drugs in the Optimal Treatment of Duodenal Ulcers

Module XIX: Design & Analysis of Clinical Trials of Antianginal Drugs

Module X: Enrichment Design & Analysis of Clinical Trials of Drugs to Treat Alzheimer's disease

Module XI: Analysis and Interpretation of Cancer Clinical Trials

Module XII: Monitoring Adverse Experiences in Clinical Drug Development

Module XIII: The Pooling of Data from Multicenter Clinical Trials

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

Module XV: 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