Washington University in St. Louis
SCHOOL OF MEDICINE

Clinical Research Training Center

Syllabus: M17-524, Spring 2018 Intermediate Statistics for the Health Sciences

About the Coursemaster

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Virtual Office Hours: If you need help with class material or have questions about assignments outside class hours, contact the teaching assistant by email. She will respond, set up a time to talk, or refer the question to the instructor if necessary.
In-Person Office Hours: We will try to include a block of 15-30 minutes at the end of each class for questions and brief consultations. If you have a larger concern, email the instructor directly (kallogjerid@wustl.edu). We will take questions during lectures, but may ask you to hold a question until the end of class if it seems not to be relevant to most of the students.

Welcome: Welcome to Intermediate Statistics for Health Sciences. My name is Dorina Kallogjeri and I am your instructor for this course. I hope that you are as excited as I am to explore more complex usage of statistics in medicine, and I look forward to meeting you all at the start of the new semester. This course is designed to build on skills developed in Introductory Statistics for the Health Sciences and to foster basic expertise required to independently use common multivariate biostatistical methods to analyze clinical research data for peer-review presentation and publication.

Coursemaster Biography: I obtained my medical degree (MD) from University of Tirana, Albania, and an MPH (Biostatistics and Epidemiology) from St. Louis University. I have over 14 years of experience in clinical research with a special interest on prediction models and clinical outcomes. I currently serve as the Research Statistician for the Department of Otolaryngology at Washington University, and I provide consulting services for researchers

in other departments at Washington University. I am also the statistical editor for JAMA Otolaryngology-Head and Neck Surgery.

During my research career, I have participated in almost all aspects of a research project, from basic data entry to writing large RO1 grants. I try to bring this breadth of experience with me into my classroom, in order to help my students better understand clinical statistics from a practical point of view.

I am the Coursemaster for the introductory-and intermediate-level medical statistics courses taught as part of the Master of Science in Clinical Investigation (MSCI) at the Clinical Research Training Center. In addition, I teach "Introduction to Statistics and Research Methods" to audiology students enrolled in the Program in Audiology and Communication Sciences. In my courses, I teach statistical concepts and model-building as applied to the clinical research field.

Teaching Philosophy:

The core of my teaching philosophy is that as students in my class, you develop the knowledge and skills that will allow you to feel comfortable using, evaluating, and continuing to learn about statistics throughout your careers as healthcare professionals. Statistics is a beautiful and powerful part of medicine, and I use my medical education and years of teaching experience to give insights into this wonderful field. My lectures are designed to expose you to important theoretical concepts, while adding nuance and understanding with examples and real life applications. Equally as important as the lectures are the practical portions of the course. I will introduce different examples and exercises for each of the topics covered in class. In addition I will demonstrate analysis of real life datasets and the interpretation of results in a format that is clinician friendly. Learning statistics is all about doing statistics. Problem sets are planned to expose you to analysis of concepts covered in class.

I have a passion for this field, and I am always available for questions, either about the course material or statistical concepts in general. I am also happy to suggest further reading for students who are interested in more advanced statistical techniques. Finally, I hope that at the end of this course, you will emerge as a better clinical researcher, and will be able communicate better and more efficiently with a statistician and with the rest of the research team.

About This Course

Required Texts:

- *Discovering Statistics Using IBM SPSS Statistics* by Andy Field, 4th ed. (Sage 2013). Lots of resources for the Field book at http://www.sagepub.com/field4e/main.htm

Optional Resources:

- *Multilevel Modeling* by Luke (Sage, 2004).
- *Survival Analysis: A Practical Approach*, 2nd ed by Machin, Cheung and Parmar (Wiley, 2006).
- *Survival Analysis: A Self-Learning Text* by Kleinbaum and Klein (2nd ed.; Springer, 2005)
- *Logistic Regression: A Self-Learning Text* by Kleinbaum and Klein (2nd ed.; Springer, 2002)
- *Applied Regression Analysis and Multivariable Methods* by Kleinbaum, Kupper, Muller, Nizam (Duxbury, 2007).

Course Description:

This 15-week course is designed to build on skills developed in *Introductory Statistics for the Health Sciences* and to foster basic expertise required to independently use common biostatistical methods to analyze clinical research data for peer-review presentation and publication. The combination of lectures, readings and hands-on work are intended to bring central concepts of multivariable statistical analysis 'down to earth' in a meaningful and applied way to clinical faculty with independent research interests. Data management will be discussed in the context both in terms of manipulating a single file or small number of files for a particular analysis, and

establishing procedures for data management within a research lab. The process of evaluating research articles, with particular emphasis on the statistics section, will also be discussed.

The course is not intended to serve as formal training in mathematics or theoretical biostatistics; neither does it seek to serve as a substitute for such training, as formulas will be discussed only briefly to illustrate key concepts. Rather, it seeks to provide a level of training and hands-on instruction that will leave students in a place in which they understand the data analytic and statistical needs in their own research, are able to confidently manage many of the core tasks related to their data analyses, and to be able to make informed decisions about when professional expertise is both necessary and worthwhile. It is the instructor's intention that upon completing the course, students will be able to comfortably handle a wide range of the analytical needs required in their research as well as be able to think critically about common multivariable data analysis techniques as they may be applied in peer-reviewed research, with a grounded sense of the scope of their abilities and limitations in the analytical domain.

Goals of the Course:

By the end of this course, you will be able to:

- Demonstrate understanding of common multivariable statistical methods used in clinical research.
- Effectively use SPSS to select and perform a variety of multivariable statistical techniques (per each of the topics covered in class)
- Comfortably read and report the results of completed analysis
- Critically review the application and interpretation of these techniques in peer-review literature.
- Work effectively with a consultant.

Technology Requirements:

All class materials will be posted to Blackboard (https://bb.wustl.edu) which you will need your WUSTL key to access. If you are having problems accessing blackboard or finding this course, please e-mail crtc@e-mail.wustl.edu.

IBM-SPSS statistics software is required for this class. Completing class assignments often requires the use of SPSS software. Bringing a laptop with SPSS to class is encouraged. For the Power and Sample Size lecture, we will use G*Power which is available for free download from http://www.gpower.hhu.de/

In addition to the book's companion website, SPSS tutorials are available online: https://stats.idre.ucla.edu/other/mult-pkg/whatstat/

You should bring an electronic calculator to class because some lectures will include exercises which are facilitated by use of a calculator. One that includes statistical functions is ideal but not necessary.

Time Requirements

For face-to-face courses in the CRTC program it is expected that you will be in class 1 hour per week for each credit of the course (i.e. this is a 3 credit course so that is 3 hours a week). In addition it is assumed you will be doing homework and reading assignments that take at least double that time. You should anticipate your time commitment for this course to be at least 9 hours a week.

Course Schedule (subject to modification)

Dates	Topic	Readings Due	Assignments Due
January 18	Data management with IBM-SPSS. Introduction to SPSS syntax	Field ch. 3, 4	
January 25	Categorical and Nonparametric Statistics	Field ch. 6, 18	
February 1	Logistic Regression 1	Field ch. 19	HW1 due
February 8	Logistic Regression 2	Field ch. 19	
February 15	Linear Regression	Field ch. 8	HW2 due
February 22	ANCOVA, Factorial ANOVA	Field ch. 12, 13	
March 1	Repeated Measures Designs Review for Midterm	Field ch. 14	HW3 due
March 8	**IN-CLASS MIDTERM**		
March 15	Spring Break – No Class		
March 22	Multilevel Analysis	Field ch. 20	HW4 due
March 29	Survival Analysis 1		
April 5	Survival Analysis 2		
April 12	Survival Analysis 3		HW5 due
April 19	Power and sample size calculations	Download G*Power for in class exercises	HW6 due
April 26	Additional Topic(s) Review for Final Exam		
May 3	**IN-CLASS FINAL EXAM**		

Assessment/Grading

30% homework (6 assignments, 5 points each)
35% midterm
35% final exam

We encourage you to work together on the homework, however the in-class exercises and quizzes and the midterm and final exam must be your work alone.

Grading Scale: This course utilizes the standard CRTC grading scale. The grade value for each letter grade is as follows:

Grades/sub-grades	4-point scale
A+ (98% to 100%)	4.00
A (93% to 97%)	4.00
A- (90% to 92%)	3.7
B+ (88% to 89%)	3.3
B (83% to 87%) – minimum for Core courses	**3.00**
B- (80% to 82%)	2.7
C+ (77% to 79%)	2.3
C (73% to 77%) – minimum for Electives	**2.00**
C- (70% to 72%)	1.7

Penalties for Late Work:
Completed homework should be printed, stapled, and labeled and is due at the beginning of class (first 15 minutes) unless otherwise instructed. No credit will be given for late homework. If you must miss a class when homework is due, please email a copy to the T.A. before the start of the class when it is due.

Attendance Requirement:
In-class participation is an important part of the coursework taken as part of the MSCI or AHBR programs and the clinical research training programs within the CRTC. Students are expected to **physically attend at least 75% of class sessions** for each course they take. Watching the videotaped class presentations is helpful to keep up with missed sessions, but is not a substitute for class attendance. Students whose professional duties or personal circumstances prevent them from meeting this program attendance requirement must receive prior written approval of the coursemaster(s), and agree on an alternate plan to achieve course objectives and earn academic credit.

Feedback and Grading Timeline:

Graded homeworks will be returned the class following homework due date. Homework keys will be posted on Blackboard the same day.

Technical Support

If you have any technical problems accessing Blackboard please e-mail crtc@email.wustl.edu. Note, this mailbox is not monitored in the evening or on weekends. If you need immediate help after hours please put a service request into https://wusm.service-now.com.

CTSA Competencies

The following Clinical and Translational Science Award (CTSA) competencies are met by this course.

Core Thematic Areas	Competencies
I. CLINICAL AND TRANSLATIONAL RESEARCH QUESTIONS	• Define the data that formulate research hypotheses. • Derive translational questions from clinical research data. • Critique clinical and translational research questions using data-based literature searches. • Extract information from the scientific literature that yields scientific insight for research innovation.
II. LITERATURE CRITIQUE	• Use evidence as the basis of the critique and interpretation of results of published studies. • Identify potential sources of bias and variations in published studies. • Interpret published literature in a causal framework. • Identify gaps in knowledge within a research problem.
III. STUDY DESIGN	• Formulate a well-defined clinical or translational research question to be studied in human or animal models. • Design a research data analysis plan. •

IV. RESEARCH IMPLEMENTATION	• Assess threats to internal validity in any planned or completed clinical or translational study, including selection bias, misclassification, and confounding. • Incorporate regulatory precepts into the design of any clinical or translational study. •
V. SOURCES OF ERROR	• Describe the concepts and implications of reliability and validity of study measurements. • Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups. • Differentiate between the analytic problems that can be addressed with standard methods and those requiring input from biostatisticians and other scientific experts. • Implement quality assurance systems with control procedures for data intake, management, and monitoring for different study designs. • Assess data sources and data quality to answer specific clinical or translational research questions. • Implement quality assurance and control procedures for different study designs and analysis.
VI. STATISTICAL APPROACHES	• Describe the role that biostatistics serves in biomedical and public health research. • Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits. • Scrutinize the assumptions behind different statistical methods and their corresponding limitations. • Generate simple descriptive and inferential statistics that fit the study design chosen and answer research question. • Compute sample size, power, and precision for comparisons of two independent samples with respect to continuous and binary outcomes. • Defend the significance of data and safety monitoring plans. • Collaborate with biostatisticians in the design, conduct, and analyses of clinical and translational research. • Evaluate computer output containing the results of statistical procedures and graphics. • Explain the uses, importance, and limitations of early stopping rules in clinical trials.
VIII. RESPONSIBLE CONDUCT OF RESEARCH	**VIII.b. Responsible Conduct of Research Competencies** • Apply the main rules, guidelines, codes, and professional standards for the conduct of clinical and translational research. • Adhere to the procedures to report unprofessional behavior by colleagues who engage in misconduct in research. •
IX. SCIENTIFIC	• Communicate clinical and translational research findings to different groups

COMMUNICATION	of individuals, including colleagues, students, the lay public, and the media. • Translate the implications of clinical and translational research findings for clinical practice, advocacy, and governmental groups. •
X. CULTURAL DIVERSITY	• Critique studies for evidence of health disparities, such as disproportional health effects on select populations (e.g., gender, age, ethnicity, race).
XIII. CROSS DISCIPLINARY TRAINING	• Apply principles of adult learning and competency-based instruction to educational activities. • Develop strategies for overcoming the unique curricular challenges associated with merging scholars from diverse backgrounds.

Course Policies

Participation (Expectations):

- It is vitally important that our classroom environment promote the respectful exchange of ideas. This entails being sensitive to the views and beliefs expressed during discussions whether in class or online.
- Your success in this course will heavily depend on your ability to communicate, engage and participate in all course activities. Successful completion of this course requires that a student keep up with all assignments and prep work for the lab components.

If you are unable to participate in the scheduled class activity or discussions you must notify the coursemaster within the week of that class module or discussion. **An unexcused failure to engage or participate with the class will be counted as an absence; unexcused absences may result in failure.** The coursemaster reserves the right to make judgment to accept and/or make–up assignments missed because of failed participation in the course activities.

Drop Dates:
If the occasion should arise that you want or need to drop this class, please see me first. You can drop for any reason during the course of the semester, however you my only receive a partial or no tuition reimbursement depending upon how far into the semester you drop the course. See the Academic Calendar for your program for specific dates and reimbursement policies. Note, late withdrawals will also appear on your transcript as a withdrawal.

CRTC Academic Policy Guidelines:

Guidelines regarding CRTC course registration and enrollment, grades, tuition obligation, and academic leave are consolidated in the CRTC Academic Policy Guidelines. Please take a moment to review this document.

CRTC Guidelines for Academic and Non-Academic Transgressions:
By registering for this course you have agreed to the terms of the CRTC Guidelines for Academic and Non-Academic Transgressions. If you have not already reviewed this policy, please be sure to before beginning any CRTC related coursework.

Academic Integrity/Plagiarism:

- Academic dishonesty is a serious offense that may lead to probation, suspension, or dismissal from the University. One form of academic dishonesty is plagiarism – the use of an author's ideas, statements, or approaches without crediting the source. Academic dishonesty also includes such acts as cheating by copying information from another student. **Plagiarism and cheating are not acceptable.**

- Academic dishonesty will be reported to the Office of the Registrar for possible action. The coursemaster will make an academic judgment about the student's grade on that work and in that course. The CRTC process regarding academic dishonesty is described in the CRTC Guidelines for Academic and Non-Academic Transgressions

Writing Assistance:
For additional help on your writing, consult the expert staff of The Writing Center in Olin Library (first floor). It can be enormously helpful to ask someone outside a course to read your essays and to provide feedback on strength of argument, clarity, organization, etc.

Disability Resources:
Washington University is committed to providing accommodations and/or services to students with documented disabilities. Washington University's Cornerstone: Center for Advanced Learning Disability Resources is the University's official resource for students with disabilities and students with suspected disabilities. DR assists students with disabilities by providing guidance and accommodations to ensure equal access to our campus, both physically and academically. To learn more about its services, initiate the process of formal documentation and/or to arrange for accommodations, please contact Disability Resources at the start of the course.

Mental Health Resources:
Mental Health Services' professional staff members work with students to resolve personal and interpersonal difficulties, many of which can affect the academic experience. These include conflicts with or worry about friends or family, concerns about eating or drinking patterns, and feelings of anxiety and depression. See: http://shs.wustl.edu/MentalHealth.

Reporting Policies:
Please also review the CRTC website for policies regarding sexual assault reporting and reporting concerns about bias, prejudice or discrimination.