

Fundamentals of Clinical and Translational Research
M17-404
COURSE SYLLABUS - Summer 2016

****Note this course is not available as an open enrollment course. Students must be accepted to the Advanced Summer Program for Investigation and Research (ASPIRE) to enroll in this course.**

INSTRUCTORS

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OFFICE HOURS

By appointment.

COURSE TIMES and LOCATION

Times: Didactic education sessions will be held during business hours, on weekdays in June, the times for each session will vary. Students are required to attend the Predoctoral Summer Seminar Series held every Friday at noon in June and July. A schedule of all classes, seminars, and events will be published and distributed during orientation.

Locations: Didactic education sessions will be held in the Clinical Research Training Center (CRTC) classroom located on the second floor of Wohl Clinics Building. The weekly Predoctoral Summer Seminar Series will be held in Erlanger Auditorium in the McDonnell Medical Sciences Building. Students will individually receive the details regarding lab locations.

TEXTBOOKS

The CRTC will loan the following textbooks to ASPIRE students:

- Discovering Statistics Using IBM SPSS Statistics by Andy Field, 4th edition. (Sage 2013). ISBN-13: 9781446249185
- Stephen Hulley et al. Designing Clinical Research. Lippincott Williams & Wilkins. 4th edition, ISBN-13: 9781608318049. This book is also available as an e-book via [Bernard-Becker Library](#).

SOFTWARE

IBM SPSS statistics software for either PC, MAC, or Linux machine will be provided by the CRTC. Students must provide the Program Coordinator with their computer's service tag or serial number in order to receive a copy of the software license.

LAPTOP

Students will perform analysis of provided data in SPSS during lab sessions so it will be very helpful if they are able to bring a laptop for use during these sessions of the Analysis of Clinical Data section.

GRADING POLICY

This is a pass/fail course. To pass the course, each student must adhere to the attendance policy outlined below, commit full-time effort to the program, and complete all assignments in a timely manner as dictated by the course instructors.

CLASS MATERIALS

Email will be the primary means of communication for the program. All course materials will be distributed electronically.

CLASS ATTENDANCE

Class participation is a vital part of ASPIRE. Students are expected to physically attend at least **75% of class sessions** for Analysis of Clinical Data and Designing Outcomes and Clinical Research Workshop. Students whose circumstances prevent them from meeting this program attendance requirement must receive prior written approval of the instructor, and agree on an alternate plan to achieve course objectives and earn academic credit. Students must notify the instructor and Pam Struttman, pstruttm@dom.wustl.edu, in advance if they will be missing a session of class.

DISABILITY POLICY

Washington University is committed to providing accommodations and/or services to students with documented disabilities. Washington University's Cornerstone: The Center for Advanced Learning Disability Resources is the University's official resource for students with disabilities and students with suspected disabilities. Disability Resources (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 DR at the start of the semester: <http://cornerstone.wustl.edu/disability-resources/>

ACADEMIC POLICIES

Registration and withdrawal deadlines and all other academic policies relating to courses offered by the CRTC can be found on the CRTC website at: http://crtc.wustl.edu/images/files/AcademicRegulations_Current.pdf.

RESPONSIBLE CONDUCT OF RESEARCH REQUIREMENT

Students are required to attend the Summer Research Program's Research Ethic's Seminar on Thursday, June 2, 2016 2:30-4PM in Farrell Learning and Teaching Center's Connor Auditorium.

COURSE DESCRIPTION

Under the direction of clinician-researchers, this course immerses the young investigators of the ASPIRE in clinical and translational research through didactic sessions, seminars, and mentored research experiences. This course is designed to introduce students to medical research and further their existing interest in the field. The two-month course encompasses three separate components, Analysis of Clinical Data, Designing Outcomes and Clinical Research Workshop, and a mentored independent clinical research experience. Students will be introduced to topics in designing outcomes and clinical research methodology, as well as basic biostatistical analysis using clinical examples, while receiving hands-on research experience. The course runs from June 1st to July 31st and is open only to students in ASPIRE.

I. MENTORED INDEPENDENT CLINICAL RESEARCH EXPERIENCE, Assigned Mentor

The mentored independent research component of this course is an exercise in practical application of the materials learned in the didactic courses and Friday seminars. Students will engage in lab meetings, presentations, and may conduct some independent clinical or translational research assigned by their mentors. The experience will allow students to gain insight into the process of conducting research and become part of the collaborative process of

sharing techniques, new endeavors, and successful investigative outcomes.

II. ANALYSIS OF CLINICAL DATA, Dr. Kallogjeri

The clinical research datasets to be analyzed are each associated with a peer-reviewed publication from a high-quality academic journal. Through reading and brief critical appraisal of the articles, students will be guided to discuss the Evidence Based Medicine (EBM) criteria for review of articles in the medical field. Each lecture will present basic statistical concepts and methods used in data preparation (manipulation) and data analysis of a research project. Data management will be discussed in the context of each project (session) with the purpose of teaching students the main concepts of data management needed for a research project as part of a research lab. Each article (session) also introduces a new method for multivariate analysis of data, and will be part of the demonstration by the instructor only.

This course will equip students with the basic expertise needed to investigate and describe data and relationships between variables in a dataset. During each laboratory session students will be analyzing datasets used for each of the articles and summarize their findings.

This is a hands-on course that illustrates basic statistical tests. Students will work with IBM SPSS statistics versions 22 or above. IBM SPSS is a user-friendly statistical software package. The best way to learn statistics is by doing statistics. This class places the students in the seat of a researcher and walks them through the logical and practical steps of a standard research project from generation of a research idea (identifying study's main objective and specific aims) to drawing conclusions based on hands-on data analysis. The course, in conjunction with other coursework focusing on clinical research design and scientific writing, will help students to better understand the clinical research field and learn to apply the obtained knowledge in real life projects.

By the end of this course students should be able to:

- Effectively use IBM SPSS statistical software to select and perform a variety of data management techniques, data description and main tests of bivariate analysis.
- Understand how to interpret the results of the above mentioned analysis.
- Identify key EBM criteria for critical review of manuscripts.

Date	Topic
Day 1	Module 2: P.C.A Louis and the Birth of Clinical Epidemiology
Day 2	Module 3: Growth and Development in Children with sickle-cell trait
Day 3	Module 4: Variability in Radiologists' interpretations of Mammograms
Day 4	Module 5: New Clinical Staging System for Cancer of the Larynx; 5-year survival rates
Day 5	Module 6: Prognostic Importance of Comorbidity in a Hospital-Based Cancer Registry

Note: Module 1 is SPSS support material for data manipulation. It is required that students read the article and prepare the critical appraisal for each Module prior to class.

III. DESIGNING OUTCOMES AND CLINICAL RESEARCH WORKSHOP, Dr. Piccirillo

Developed by Dr. Piccirillo, this workshop is based on the Designing Clinical Research course developed by Dr. Stephen Hulley and colleagues at the University of California - San Francisco School of Medicine. The goal of the workshop is to teach the methods of clinical investigation to young investigators. This section of the course is taught in five two-hour sessions during June, and concludes with the submission of a five-page research proposal and final research presentations in July.

Please note specific session topics, homework assignments, and partner assignments will be detailed in the handbook students will receive at orientation. Students should pay close attention to the deadlines and schedule for final presentations and research protocols.

5-page Research Protocol Due to Pam Struttman in mid-July, the exact date will be listed in the program schedule.

PROTOCOL DEVELOPMENT

1. **No more than 5-pages. There is an absolute limit of 5 pages of text, single space and size 12 font, plus up to an additional 5 pages of references.** The reason for these constraints is not so much to reduce the size of each student's creative task as it is to make the task of critiquing each other's protocols a manageable one. The 5-page limit makes for a considerably more concise protocol than an NIH submission, but is not so different from what is expected for a research training position or small intramural grant. The need to be concise will focus each student's approach to planning the study. If necessary students may summarize the ways he/she would flesh some parts of the text out in a longer version.
2. **Final protocol is due in mid-July; the date will be posted on the program schedule.** The protocol must be sent as a Microsoft Word attachment to Pam Struttman at pstruttm@dom.wustl.edu .

The next page provides a suggested outline indicating a good way to allocate the five pages (to help avoid such things as spending too much space on the Significance and then neglecting key nitty-gritty aspects of the Methods).

5 Page Protocol Suggested Outline

Title

Abstract

Statement of Research Problem (500 words or less)

Specific aims/Hypothesis(es) to be tested

Significance (limit this to 1/2 page)

Methods (approximately 1000 words)

- Overview of design
 - time frame and nature of control
- Study subjects
 - selection criteria, target and accessible populations
 - plans for sampling and for recruiting subjects
- Measurements
 - predictor variables (intervention, if an experiment and potential confounders)
 - outcome variables
- Pretest plans
- Statistical issues
 - hypotheses and sample size estimates
- Quality control and data management

Ethical considerations

References (not included in the 5-page limit)

Appendices (do not include)