

CLINICAL RESEARCH SCHOLARS PROGRAM (CRSP)

Case Western Reserve University (CWRU)

CRSP COURSE DESCRIPTIONS

For current offerings/substitutions/schedule/classrooms, please view <https://www.case.edu/registrar/registration/schedule-of-classes/> - Schedule of Classes.
Select the semester of interest, type the first four LETTERS OF THE COURSE CODE (e.g., CRSP) in the first available field and submit

COURSE NAME, NUMBER, & SEMESTER	DESCRIPTION – TOPICS - REQUIREMENTS	LOCATION OF COURSE AND SCHEDULE	INSTRUCTOR OR COURSE DIRECTOR	CONTACT INFORMATION
CRSP 401 Introduction to Clinical Research Summer Series Credit Hours: 1-3 Summer Semester	Introduction to clinical research and overview of Master’s program. This course is designed to familiarize students with the language and concepts of clinical investigation and statistical computing, as well as provide opportunities for problem-solving and practical application of the information derived from the lectures. The material is organized along the internal logic of the research process, beginning with mechanisms of choosing a research question and moving into the information needed to design the protocol, implement it, analyze the findings, and draw and disseminate the conclusion(s). <i>Text: Hulley et. al.: Designing Clinical Research - ISBN 0-7817-2218-7</i> <i>Software: None</i>	Consult http://www.cwr.edu/pr ovost/registrar/registrar .html - select Schedule of Classes Case School of Medicine	Douglas Einstadter, MD, MPH	deinstadter@metrohealth.org or 216-778-3902
CRSP 402 Study Design and Epidemiologic Methods Credit Hours: 3 Fall Semester	This course covers the methods used in the conduct of epidemiologic and health services research. The course begins with how to quantify disease frequency and compare it across populations, often as a way to generate hypothesis about what factors may cause a given condition. The course will introduce methodologic issues that need to be considered in the design and conduct of epidemiologic studies, including classification of disease and exposure status, types and consequences of misclassification, effect modification and related concepts. Additional sessions will focus on the control of confounding and on the three main types of study designs: randomized trials, cohort studies and case-control studies. Topics include: Measures of disease frequency, measures of effect, classification and misclassification, cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, confounding, bias, effect modification and select topics. <i>Prereq: CRSP 401 or consent of instructor – permit required</i> <i>Suggested Text: Hennekens CH, Buring JE. (1987). Epidemiology in Medicine, Little, Brown and Company.</i>	Consult http://www.cwr.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	Douglas Einstadter, MD, MPH	deinstadter@metrohealth.org or 216-778-3902

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CRSP 406 Introduction to R Programming Credit Hours: 2 Summer Semester	<p>This course will provide students with an introduction to R (Version 3.0 or higher). Major topics will include session management, reading and writing data, R data objects, combining and restructuring data frames, handling missing data, working with dates, statistical analysis concepts, data aggregation, statistical functions, and R traditional graphics. Students will learn R programming conventions, how to troubleshoot R code, as well as how to interpret R output. Small research datasets will be used in class examples, computer laboratory sessions, and homework assignments. Each session will include a lecture immediately followed by a computer lab to reinforce the concepts introduced. Students will work in small groups or individually.</p> <p>Prereq: Instructor's consent required Texts: Zuur, Alain F. (2009). <i>A Beginners Guide to R</i>. Springer. Dalgaard, Peter (2008). <i>Introductory Statistics with R, 2nd ed.</i> Springer Software: Latest versions of R and RStudio software installed</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	Steven Lewis, MS, MBA	Sal25@case.edu
CRSP 410 Independent Study in Clinical Research Credit Hours: 1-3 All Semesters	<p>This course enables the student to undertake study of advanced topics in clinical research that are not offered as standing courses at CWRU. The student(s) and a member of the CRSP faculty, or another faculty member at CWRU, submit a 1-2 page proposal for independent study to the CRSP Program Director. The proposal should include a descriptive title (e.g., research method or clinical topic area) to be studied; a list of up to 5 student-centered objectives of the study; how the subject matter will be learned; and how success in achieving the objectives will be measured (e.g., manuscript, essay, grant proposal, or other written product; examination, etc). It is expected that there will be approximately one contact hour per week for each credit hour requested.</p> <p>Prereq: Consent of CRSP Department</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes or your instructor or CRSP faculty advisor	James Spilsbury, PhD	ics5@case.edu
CRSP 412 Communication in Clinical Research – Grant Writing Credit Hours: 1 Spring Semesters	<p>Written communication is a critical skill in clinical science. We disseminate our work to others through publications, and we obtain the resources to conduct research through grant proposals. This course has been developed for KL2 and CRSP scholars. The course focuses on writing grant proposals and, in particular, specific sections of an NIH-style grant. However, the principles discussed in the course apply to any type of proposal.</p> <p>Prereq: CRSP 401 or equivalent and instructor's consent required</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	James Spilsbury, PhD	ics5@case.edu

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CRSP 413 Communication in Clinical Research – Oral Presentation, Posters, & the Mass Media Credit Hours: 1 Fall Semesters	To move their work forward, investigators must be able to present their research effectively to both scientific and lay audiences. Although “the written word” is probably the first medium that comes to mind when we think of communication in scientific circles, other modes of communication are also vital. The main objective of this course is to help scholars improve their oral and poster presentation skills, as well as interactions with the mass media. This objective will be achieved through a combination of didactic sessions, readings, and presentations by the students. Prereq: <i>Instructor’s consent required</i>	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	James Spilsbury, PhD	cs5@case.edu
CRSP 431 Statistical Methods I Credit Hours: 3 Fall Semester	Application of statistical techniques with particular emphasis on problems in the biomedical sciences. Basic probability theory, random variables, and distribution functions. Point and interval estimation, regression, and correlation. Problems whose solution involves using packaged statistical programs. Prereq: <i>Instructor’s consent required</i> <i>Offered as ANAT 431, BIOL 431, CRSP 431, PQHS 431, and MPHP 431</i>	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	Thomas E. Love, PhD	thomas.love@case.edu
CRSP 432 Statistical Methods II Credit Hours: 3 Spring Semester	Methods of analysis of variance, regression, and analysis of quantitative data. Emphasis on computer solution of problems drawn from the biomedical sciences. Design of experiments, power of tests, and adequacy of models. Prereq: <i>Instructor’s consent required</i> <i>Offered as BIOL 432, CRSP 432, PQHS 432, and MPHP 432</i>	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	Thomas E. Love, PhD	thomas.love@case.edu
CRSP 440 Translational & Patient- Oriented Research Theory Credit Hours: 3 Fall Semesters	This course provides an overview of the theoretical framework, rationale, process, methodologies, and ethics of clinical and translational research. An integral feature of this course is the participation of a multidisciplinary teaching team, whose expertise and perspective will contribute to providing real-world insights into the complexities of translational and patient-oriented research. Prereq: <i>Instructor’s consent required</i>	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html	James Spilsbury, PhD	james.spilsbury@case.edu

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CRSP 450 Seminar in Multidisciplinary Clinical and Translational Research Credit Hours: 0 Each Semester	<p>The purpose of this monthly seminar is to introduce students to the processes and challenges of multidisciplinary clinical/translational science, through which discoveries in the laboratory or in early clinical studies are transformed into interventions, treatments, and ultimately, best practices and policies on national and international levels. The seminar will use a case-based approach. Examination of active projects at CWRU, Cleveland Clinic Foundation, the MetroHealth Medical Center, University Hospitals, and Louis Stokes Veterans Administration Medical Center will enable students to learn first-hand about clinical translational science in action.</p> <p>Prereq: <i>Instructor's consent required</i></p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html	Li Li, PhD	Li.Li@case.edu
CRSP 500 Design and Analysis of Observational Studies Credit Hours: 3 Spring Semester	<p>An observational study is an empirical investigation of treatments, policies or exposures and the effects that they cause, but it differs from an experiment because the investigator cannot control treatment assignment. We introduce appropriate design, data collection and analysis methods appropriate for clinical investigators, preparing students to design and interpret their own studies, and those of others in their field. Technical formalities are minimized, and the presentations will focus on the practical application of methodologies and strategies. A course project involves the completion of an observational study, and substantial use of the R statistical software. Topics include randomized experiments and how they differ from observational studies, planning and design for observational studies, adjustments for overt bias, sensitivity analysis, methods for detecting hidden bias, and propensity score methods for selection bias adjustment, including multivariate matching, stratification, weighting and regression adjustments, along with some comparison of these methods with instrumental variables approaches.</p> <p>Prereq: <i>Instructor's consent required</i></p> <p>Recommended preparation: <i>a working knowledge of multiple regression, some familiarity with logistic regression, and some exposure to fitting such models in R.</i></p> <p>Syllabus & Course Material: https://sites.google.com/a/case.edu/love-500/home/course-materials-and-handouts</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	Thomas E. Love, PhD	thomas.love@case.edu

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CRSP 501 Team Science -Working in Interdisciplinary Research Teams Credit Hours: 1 Fall Semester	<p>This course will assist learners to understand why and how different professional disciplines, each representing a body of scientific knowledge, can best work together to develop and disseminate translational knowledge. Learners will develop a set of skills specific to be an effective member and leader of an interdisciplinary research team, including working with different value and knowledge sets across disciplines, understanding the mental models of other disciplines, creating shared mental models, running effective meetings, managing conflict, giving and receiving feedback, and group decision making techniques. Using the small group seminar approach and case studies, learners will practice individual and group communication, reflective and self-assessment techniques, and engage in experiential learning activities regarding effective teamwork in interdisciplinary research teams. Techniques to increase group creativity and frame new insights will be discussed.</p> <p>Prereq: <i>K grant appointment and instructor's consent required</i></p>	Consult http://www.cwru.edu/pr-ovost/registrar/registrar.html - select Schedule of Classes	Shirley Moore, RN, PhD	shirley.moore@case.edu
CRSP 502 Leadership Skills for Clinical Research Teams Credit Hours: 2 Spring Semester	<p>This semester-long course uses methods of Intentional Change Theory to engage students in a series of self-assessment activities to gain insights into their behavior and its effect on others, and to learn a set of skills to be an effective member and leader of an interdisciplinary research teams. Such skills include working with different values and knowledge sets across disciplines, running effective meetings, conflict management, giving and receiving feedback, and group decision making techniques. This small group series of sessions includes case-based learning and sequentially introduces three sets of sessions: at the conclusion of the first sets, Scholars develop a Personal Vision essay; the second sets, a Personal Balance Sheets, and in the third set, a Personal Learning Plan, including components leading to effective leadership skills and skill building in teamwork. As an example, the focus of a case study in developing a “program project”-type grant proposal highlights the effect of disciplinary-specific language on multidisciplinary research team functioning, and the needs for and methods to create a “common language” for team use.</p> <p>Prereq: <i>K grant appointment and instructor's consent required</i></p>	Consult http://www.cwru.edu/pr-ovost/registrar/registrar.html - select Schedule of Classes	Philip Cola, PhD	Philip.cola@uhospitals.org

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CRSP 503 Innovation and Entrepreneurship Credit Hours: 1 Summer Semester	<p>This module is to acquaint and ultimately engage clinical researchers with the business of innovation and entrepreneurship. Goals include: (1) provide researchers with many of the skills that they would need to translate academic research into commercial uses; (2) sensitize clinical researchers to the goals of the business community and facilitate their ability to work with the private sector on technology development; and (3) make clinical researchers aware of the processes of academic technology development and transfer. Sessions consist of a lecture and case discussion facilitated by one of the co-directors.</p> <p>Prereq: Consent of course director Course pack: Available from www.hbsp.harvard.edu</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	Scott Shane, PhD	Sas46@case.edu
CRSP 504 Managing Research Records - A System's Approach Credit Hours:2 - 3 Spring Semester	<p>This course will provide an approach to managing data for research studies. Major topics will include a discussion of a research study system including database design and development, data management, and clinical data management; how to evaluate the data needs of a study including the impact of required regulations; summary of key regulations; the role of the data manager including protocol review, development of a data management plan, CRF design, data cleaning, locking studies and ensuring best practices. Each session will include a lecture, class discussion, and student presentation.</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	Carolyn Apperson-Hansen, MStat	cva9@case.edu
CRSP 505 Investigating Social Determinants of Health Credit Hours:2-3 Spring Semester	<p>The biopsychosocial model highlights the inter-related roles that biological, psychological, and social factors play in health and illness. This course is geared towards clinical research scholars who would like to incorporate aspects of the "social context" in their research. This course will examine the conceptualization and measurement of several key socio-cultural determinants of health and illness. This course is organized by social determinant. Each session focuses on a specific social determinant or set of related determinants. The session examines how the determinant is conceptualized (including relevant theoretical models or frameworks), how it is measured, and the challenges researcher face as they incorporate the social determinant in their research. Sample studies that incorporate social determinants of health will be reviewed. This course will also consider strategies and techniques to conduct clinical research involving social factors in socially and ethnically diverse settings. Students will be encouraged to develop a prototypical study design to incorporate social determinants in their research.</p> <p>Recommended preparation: CRSP 401 and instructor's consent</p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	James Spilsbury, PhD	ics5@case.edu

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CRSP 510 Health Disparities Credit Hours: 3 Fall Semester	<p>This course aims to provide theoretical and application tools for students from many disciplinary backgrounds to conduct research and develop interventions to reduce health disparities. This course will be situated contextually within the historical record of the United States, reviewing social, political, economic, cultural, legal, and ethical theories related to disparities in general, with a central focus on health disparities. Several frameworks regarding health disparities will be used for investigating and discussing the empirical evidence on disparities, research and outcome measurement issues, policy and policy formation concerns, and intervention practices. While racial/ethnic disparities in health and health outcomes will be an important focus of this course, disparities among other subgroups (e.g., the poor, women, uninsured, disabled, and non-English speaking populations) will also be included and discussed. Students will be expected to develop a research proposal (observational, clinical, and/or intervention) rooted in their disciplinary background that will incorporate materials from the various perspectives presented throughout the course, with the objective of developing and reinforcing a more comprehensive approach to current practices within their fields.</p> <p>Prereq: <i>Instructor's consent required – contact Dr. Sudano</i> <i>Offered as CRSP 510, EPBI 510, MPHP 510, NURS 510, and SASS 510</i></p>	Request schedule from Dr. Sudano or consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	Joseph J. Sudano, Jr., PhD and Ash Sehgal, MD	jsudano@metrohealth.org axs81@cwru.edu
CRSP 550 Meta-Analysis and Evidence Synthesis Credit Hours: 2 – 3 Spring Semester	<p>This course is designed to introduce students to the methods of conducting a high quality systematic review. We will cover the design, methods, and analytic techniques involved in systematic reviews. These concepts will prepare students to conduct their own systematic review or evaluate the systematic reviews of others. Sessions will mainly include problem-based learning supplemented by lectures.</p> <p>Topics include developing a search strategy, abstracting key data, synthesizing the results qualitatively and quantitatively, meta-analytic techniques, grading the quality of studies, grading the strength of the evidence, and manuscript preparation specific to systematic reviews.</p> <p>Offered as CRSP 550 and PQHS 550.</p> <p>Prereq: <i>CRSP 401, MPHP 405, PQHS 431, NURS 532 or equivalent and Instructor's consent required</i></p>	Consult http://www.cwru.edu/pr ovost/registrar/registrar.html - select Schedule of Classes	TBA	

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CRSP 560 Special Topics in Clinical Research Credit Hours: 2 All Semesters	In this variable 1-3 credit hour course, students will explore particular issues and themes related to Clinical Research. The course content will vary and is designed to explore content not covered in other CRSP courses or to expand student knowledge on topics introduced by other CRSP courses.	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	TBA	
CRSP 603 Research Ethics and Regulation: Emerging Issues and Ongoing Challenges Credit Hours: 1 - 2 Fall Semester	This course designed to introduce students to the ethical, policy, and legal issues raised by research involving human subjects. It is intended for law students, post-doctoral trainees in health-related disciplines and other students in relevant fields. Topics include (among others): regulation and monitoring of research; research in third-world nations; research with special populations; stem cell and genetic research; research to combat bioterrorism; scientific misconduct; conflicts of interest; commercialization and intellectual property, and the use of deception and placebos. The course will meet once per week for two hours over the semester. Grades will be given based on class participation and a series of individual and group projects. Prereq: Instructor's consent required Text: Coleman, C et. al. (2005). <i>The Ethics and Regulation of Research with Human Subjects</i> . Offered as BETH 503 and LAWS 603	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	Patricia Marshall	patricia.marshall@case.edu
CRSP 650 Capstone/Internship Project Credit Hours: 3 All Semesters	This course will provide hands-on experience in conducting clinical research. The student will dedicate at least 160 hours over the course of a semester. Under the guidance of a Capstone Advisor, the student will develop a project or internship/practicum, which may take diverse forms: <ul style="list-style-type: none"> • A study project • Internship/Practicum: A combination of tasks necessary for the successful implementation of a study, such as attending team meetings, developing an IRB protocol, designing study forms, assisting with recruitment, study procedures, data management/cleaning, descriptive analysis, secondary analysis • Another format, with approval of the CRSP director and Capstone Advisor 	Consult http://www.cwru.edu/pr ovost/registrar/registrar .html - select Schedule of Classes	CRSP Faculty Advisor	

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CRSP 651 Thesis Research Credit Hours: Variable, 1 to 18 Fall/Spring/Summer Semesters	Thesis development and research towards the Master's degree, including defense of the thesis proposal and final oral and written defense of research. Prereq: Consent of CRSP faculty advisor	Consult http://www.cwru.edu/prvost/registrar/registrar.html	CRSP Faculty Advisor	
PQHS 411 (Previously known as EPBI 411) Introduction to Behavioral Health Credit Hours: 3 Spring Semester	Using a biopsychosocial perspective, the course provides an overview of the measurement and modeling of behavioral, social, psychological, and environmental factors related to disease prevention, disease management, and health promotion is provided. Prereq: Instructor's consent required <i>Offered as PQHS 411 and MPHP 411</i>	Consult http://www.cwru.edu/prvost/registrar/registrar.html - select Schedule of Classes	As per Schedule of Classes	Instructor
PQHS 450 (Previously known as EPBI 450) Clinical Trials and Intervention Studies Credit Hours: 3 Spring Semester	Issues in the design, organization, and operation of randomized, controlled clinical trials and intervention studies. Emphasis on long-term multicenter trials. Topics include legal and ethical issues in the design; application of concepts of controls, masking, and randomization; steps required for quality data collection; monitoring for evidence of adverse or beneficial treatment effects; elements of organizational structure; sample size calculations and data analysis procedures; and common mistakes. Recommended preparation: PQHS 431 or consent of instructor <i>Offered as EPBI 450 and MPHP 450</i>	Consult http://www.cwru.edu/prvost/registrar/registrar.html - select Schedule of Classes	As per Schedule of Classes	Instructor

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<p>PQHS 467 (Previously known as EPBI 467)</p> <p>Comparative and Cost Effectiveness Analysis in Health Care</p> <p>Credit Hours: 3</p> <p>Summer Semester</p>	<p>Comparative effectiveness research is a cornerstone of healthcare reform. It holds the promise of improved health outcomes and cost containment. This course is presented in a convenient 5-day intensive format in June. There are reading assignments due prior to the 1st session.</p> <p>Module A (Days 1-2): Overview of comparative effectiveness research (CER) from a wide array of perspectives: individual provider, institution, insurer, patient government, and society. Legal ethical and social issues, as well as implications for population and public health, including health disparities will also be component.</p> <p>Module B (Day 3): Introduction to the various methods, and their strengths, weaknesses and limitations. How to read and understand CER papers.</p> <p>Module C (Days 4-5): Cost-Effectiveness Analysis. This will cover costing, cost analysis, clinical decision analysis, quality of life and cost-effectiveness analysis for comparing alternative health care strategies. Trial version of TreeAge software will be used to create and analyze a simple cost-effectiveness model.</p> <p>Take all 3 modules for full 3 credits. Modules A or C can be taken alone for 1 credit. Modules A and B or Modules B and C can be taken together for a total of 2 credits. Module B cannot be taken alone. If taken for 2 or 3 credits, some combination of term paper, project and/or exam will be due 30 days later.</p> <p><i>Offered as EPBI 467 and MPHP 467</i></p>	<p>Consult http://www.cwru.edu/prvost/registrar/registrar.html - select Schedule of Classes</p>	<p>As per Schedule of Classes</p>	<p>Instructor</p>

*To obtain software, click on <http://softwarecenter.case.edu/>
Key: TBA = to be approved