CLINICAL RESEARCH SCHOLARS PROGRAM (CRSP)

CRSP 401. Introduction to Clinical Research Summer Series. 3 Units.
This course is designed to familiarize one 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). Prereq: M.D., R.N., Ph.D., D.D.S., health professionals.

CRSP 406. Introduction to R Programming. 3 Units.
This course will provide students with an introduction to R. Major topics will include session management, data objects, reading and writing data, restructuring and combining data frames, handling missing data, working with dates, statistical analysis concepts, and R traditional graphics. Students will learn R programming conventions, how to create, manage and edit R scripts programs, and how to interpret output. Each class will consist of a demo on each lesson followed by a practice session when time permits. Small research datasets will be used both in class examples and in the exercises for each lesson. Students will be expected to complete all homework assignments on time and submit a take-home final exam.

CRSP 410. Independent Study in Clinical Research. 1 - 3 Units.
Independent Study in Clinical Research enables the student to undertake study of advanced topics in clinical research that are not offered as standing courses at Case Western Reserve University. The student(s) and a member of the Clinical Research Scholars Program 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 at least one contact hour per week for each credit hour requested.

CRSP 412. Communication in Clinical Research - Grant Writing. 1 Unit.
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. Prereq: CRSP 401 or equivalent.

CRSP 413. Communication in Clinical Research - Oral Presentation, Posters, and the Mass Media. 1 Unit.
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 interaction with the mass media. This objective will be achieved through a combination of didactic sessions, readings, and presentations by the students. Prereq: CRSP 401 or equivalent.

CRSP 431. Statistical Methods I. 3 Units.
This course is the first half of a two-semester sequence focused on modern data analysis, advanced statistical modeling, and programming in R and R Markdown. The course emphasizes placing biological, medical and health research questions into a statistical context, and thinking effectively about practical questions of design and analysis, while minimizing theory. In the first semester, we use tools from the tidyverse and literate programming to produce replicable research on public data. Course projects focus on using modern tools to ingest, tidy, manage, explore (transform, visualize and model) and communicate about data. Foundations of the first semester include exploratory data analysis, estimation strategies for means and proportions, and linear models for prediction and exploration of quantitative outcomes. The course attracts people with varied backgrounds in statistics/data science or coding/programming or biomedical science, and a common interest in using data effectively in scientific research. Instructor permission is required for enrollment. Offered as CRSP 431, MPHP 431, and PQHS 431.

CRSP 432. Statistical Methods II. 3 Units.
This course is the second half of a two-semester sequence focused on modern data analysis, advanced statistical modeling, and programming in R and R Markdown. The course emphasizes placing biological, medical and health research questions into a statistical context, and thinking effectively about practical questions of design and analysis, while minimizing theory. Course projects focus on using modern tools to ingest, tidy, manage, explore (transform, visualize and model) and communicate about data. Foundational topics discussed in the second semester build on the work done in the first, and include data spending, estimating and assessing models built with multiple engines in replicable ways using the tidymodels framework, as well as logistic regression and generalized linear models for counts and multi-categorical data, and introductions to modeling weighted, time-to-event and multi-level data. The prerequisite is Statistical Methods I, but well-prepared students may seek a waiver from the instructor. Offered as CRSP 432, MPHP 432, and PQHS 432. Prereq: CRSP 431.

CRSP 440. Translational & Patient-Oriented Research Theory. 3 Units.
Clinical (patient-oriented) and translational science has emerged as a new scientific discipline aimed to accelerate scientific discovery into effective practice. 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.

CRSP 450. Seminar in Multidisciplinary Clinical & Translational Research. 0 Unit.
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 Case Western Reserve University, Cleveland Clinic Foundation, the MetroHealth Medical Center, University Hospitals Case Medical Center, and the Louis Stokes Veterans Administration Medical Center will enable students to learn first-hand about clinical translational science in action.

CRSP 500. Design and Analysis of Observational Studies. 3 Units.
An observational study investigates treatments, policies or exposures and the effects that they cause, but it differs from an experiment because the investigator cannot control assignment. We introduce appropriate design, data collection and analysis methods for such studies, to help students 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 the ideas. 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 focus on propensity score methods for selection bias adjustment, including multivariate matching, stratification, weighting and regression adjustments. Recommended preparation: a working knowledge of multiple regression, some familiarity with logistic regression, with some exposure to fitting regression models in R. Offered as CRSP 500 and PQHS 500.

CRSP 501. Team Science - Working in Interdisciplinary Research Teams. 1 Unit.
This course will assist learners to understand 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.

CRSP 502. Leadership Skills for Clinical Research Teams. 2 Units.
Leadership Assessment and Development is for participants to learn a method for assessing their knowledge, abilities, and values relevant to management; and for developing and implementing plans for acquiring new management related knowledge and abilities. The major goals of this course include generating data through a variety of assessment methods designed to reveal your interests, abilities, values, and knowledge related to leadership effectiveness; learning how to interpret this assessment data and use it to design/plan developmental activities; small group sharing of insights from the various assessments. Recommended preparation: K grant appointment or consent of instructor.

CRSP 503. Innovation and Entrepreneurship. 1 Unit.
The purpose of this module is to acquaint and ultimately engage clinical researchers with the business of innovation and entrepreneurship. Goals include: (1) to provide researchers with many of the skills that they would need to translate academic research into commercial uses: (2) to 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) to 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.

CRSP 504. Managing Research Records - A System's Approach. 2 - 3 Units.
This course will provide an approach to managing data for research studies. Major topics 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.

CRSP 510. Health Disparities. 3 Units.
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. The 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 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. Offered as CRSP 510, PQHS 510, MPHP 510, NURS 510, and SASS 510.

CRSP 529. FDA Regulation in Entrepreneurship and Clinical Research. 0 - 3 Units.
The FDA Regulation in Entrepreneurship and Clinical Research course is designed to provide foundational knowledge in the FDA approval and regulatory process while highlighting scientific, clinical, ethical, and other related emergent factors for consideration. The course includes a series of lecture-based classes delivered by content experts and interdisciplinary team-based learning discussions of case studies designed for the application of lecture content. Students who elect to take the course for three credits as opposed to one credit will go through the process of reviewing an example Investigational New Drug (IND) or Investigational Drug Exemption (IDE) Application (midterm project) and preparing an IND or IDE for submission (final project) with the guidance of nationally renowned experts in FDA regulation and law. The primary goal of this course is that upon completion, students will be able to take the knowledge gained from content experts and apply it to facilitate the movement of their current or future technologies through the FDA approval process. Offered as CRSP 529, PHRM 529 and RGME 529.

CRSP 550. Meta-Analysis & Evidence Synthesis. 2 - 3 Units.
Systematic reviews use reproducible methods to systematically search the literature and synthesize the results of a specific topic area. Meta-analysis is a specific analytic technique used to pool results of individual studies. Systematic reviews are useful ways to establish one's knowledge in a particular field of study, and can highlight gaps in research which can be pursued in future work. They can also inform the background of a grant. This course is designed to introduce students to the methods of conducting a high quality systematic review and meta-analysis of intervention studies. 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 be lectures, labs, and presentations. Topics include developing a search strategy, abstracting key data, synthesizing the results qualitatively, meta-analytic techniques, grading the quality of studies, grading the strength of the evidence, and manuscript preparation specific to systematic reviews and meta-analysis of intervention studies. Caveat: If you would like to conduct a systematic review of your own that can be published after the course ends, you will need to have several other class members or colleagues willing to work with you on the project. The systematic review should be on a topic where you expect no more than 20-30 included studies in order to be able to complete the review soon after the course ends. Offered as CRSP 550 and PQHS 550. Prereq: CRSP 401, PQHS/EPBI 431, MPHP 405, NURS 532 or Requisites Not Met permission.

CRSP 560. Special Topics in Clinical Research. 1 Unit.
In this 1 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.

CRSP 601. Research Practicum. 1 - 9 Units.
Research practicum and/or laboratory rotation.

CRSP 603. Research Ethics and Regulation. 1 - 2 Units.
This course is 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. Course will meet once per week for 2 hours throughout the semester. Grades will be given based on class participation and a series of group projects and individual short writing assignments. Offered as BETH 503, CRSP 603 and LAWS 5225.

CRSP 650. Capstone Experience. 3 Units.
The Capstone will provide hands-on experience in conducting clinical research. To complete the Capstone project the student will register for 3 credit hours and dedicate at least 160 hours over the course of a semester, typically 20 hours per week for 8 weeks. Under the guidance of a Capstone Advisor the student will develop a Capstone project or internship/practicum, which may take diverse forms: 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 CRSP director and Capstone Advisor.

CRSP 651. Thesis M.S.. 1 - 18 Units.
(Credit as arranged.)

CRSP 701. Dissertation Ph.D.. 1 - 9 Units.
Ph.D. Dissertation credits. Prereq: Predoctoral research consent or advanced to Ph.D. candidacy milestone.