Clinical Investigation

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Courses

CLNV 4060 Statistics for Step Up Scholars

Students will be introduced to basic biostatistical analysis using clinical examples, while receiving hands-on research experience. This course is only open to R25 STEP-UP Scholars

Credit 1 unit.

Typical periods offered: Fall, Summer

CLNV 4100 Fundamentals of Clinical and Translational Research

Under the direction of clinician-researchers, this course immerses young investigators in clinical research though didactic sessions, seminars and mentored research experiences. Students will be introduced to topics in designing outcomes and clinical research as well as basic biostatistical analysis using clinical examples, while getting hands-on research experience. Open only to students in the Advanced Summer Program for Investigation and Research Education (ASPIRE).

Credit 3 units.

Typical periods offered: Summer

CLNV 4101 Designing Outcomes & Clinical Research for R25 Scholars

Under the direction of clinician-researchers, this course immerses the young investigators 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 up to two separate components: Designing Outcomes and Clinical Research Workshop, a and 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 handson research experience. This course is only open to students in the R25 program.

Credit 2 units.

Typical periods offered: Summer

CLNV 5040 PIRTT Mentored Independent Research

Trainees earn Predoctoral Interdisciplinary Clinical Research Training Mentored Independent Research credits for conducting clinical research, completing a report and developing and presenting a poster describing their work. They are also expected to attend a half-day research symposium in the fall with other clinical investigators. Mentored Independent Research will be presented each semester to an advisory committee that includes the scholar's departmental mentors as well as Clinical Research Training Center program faculty. The research presented will be in the form of a research paper submitted for publication in a peer reviewed journal. Under some circumstances, a grant application submitted for review will be acceptable in place of the research paper. PICRT Mentored Independent Research will provide scholars with the practical application of skills learned in the Clinical Research Training Program didactic coursework and seminars. Open to CRTC Predoctoral Program scholars only.

Credit 1-8 units.

Typical periods offered: Fall, Spring, Summer

CLNV 5050 Designing Clinical Research Workshop

Designing Clinical Research Workshop is a new eight-week course developed by Dr. Piccirillo, and is based on the Designing Clinical Research Course developed by Dr. Hulley and colleagues at the University of California - San Francisco School of Medicine. The course is taught in conjunction with the textbook, Designing Clinical Research, 2nd Edition (Hulley et al, Lippincott, Williams and Wilkins, 2001). The goal of the course is to teach the methods of clinical investigation to physicians and other health professionals. The main part of the course runs in seven sessions, with a lot of active homework and two hours a week in class. Topics include: The Anatomy and Physiology of Clinical Research; Conceiving the Research Questions; Choosing the Subjects: Specification, Sampling & Recruitment; Planning the Measurements: Precision and Accuracy; Getting Ready to Estimate Sample Size: Hypotheses & Underlying Principles; Estimating Sample Size and Power; Designing an Observational Study - cohort, crosssectional, and case-control studies; Enhancing Causal Inference in Observational Studies; Designing an Experiment - clinical trials; Designing Diagnostic and Prognostic Test Studies; Secondary Data Analysis; Designing Questionnaires and Data Collection Instruments; Implementing the Study; Data management; and Writing and Funding a Research Protocol. Open to CRTC Predoctoral Program scholars only.

Typical periods offered: Summer

CLNV 5070 Ethical and Legal Issues in Clinical Research

This course prepares clinical researchers to critically evaluate ethical and regulatory issues in clinical research. The principal goal of this course is to prepare clinical researchers to identify ethical issues in clinical research and the situational factors that give rise to them, to identify ethics and compliance resources, and to foster ethical problem-solving skills. The course aims to deliver practical guidance for investigators through discussion of critical areas of clinical research ethics. An additional aim of the course is to enable participants to recognize the different ways in which research participants may be vulnerable and the ethical issues raised by including and excluding vulnerable participants. By the end of the course, participants will understand the regulatory framework that governs human subjects research and the distinction between compliance and ethics; be able to identify major ethical concerns in the conduct of clinical research, including situational factors that may give rise to ethical concerns; and be able to apply an ethical problem-solving model in clinical research. Please contact the MSCI Program for permission to enroll in this course. Credit 2 units.

Typical periods offered: Fall

CLNV 5100 Designing Outcomes and Clinical Research

This course covers how to select a clinical research question, outline a research protocol, and execute a clinical study. Topics include: subject selection, observational and experimental study designs, sample size estimation, clinical measurement, bias and confounding, and data management. The course is designed for health care professionals who wish to conduct patient-oriented clinical research. Students incorporate research design concepts into their own research proposal. The course consists of lectures, weekly problem sets, weekly reading assignments, outlining a research protocol, and a final exam.

Credit 3 units.

Typical periods offered: Fall

Washington University in St. Louis

CLNV 5110 MTPCI Mentored Independent Research

Scholars earn Mentored Independent Research credits for conducting clinical research, completing a report and developing and presenting a poster describing their work. They are also expected to attend a half-day research symposium in the fall with other clinical investigators. Mentored Independent Research will be presented each semester to an advisory committee that includes the scholar's departmental mentors as well as Clinical Research Training Center program faculty. The research presented will be in the form of a research paper submitted for publication in a peer reviewed journal. Under some circumstances, a grant application submitted for review will be acceptable in place of the research paper. MTPCI Mentored Independent Research will provide scholars with the practical application of skills learned in the Clinical Research Training Program didactic coursework and seminars. Open to CRTC Postdoctoral Program scholars only.

Credit 1-8 units.

Typical periods offered: Fall, Spring, Summer

CLNV 5120 PIRTT Research Seminar

Pre/Postdoctoral Interdisciplinary Research Training in Translation (PIRTT) Seminar. Two semesters of this course are required for the TL1 Scholars. This course alternates faculty presentations, research-in-progress discussions, and reading and journal discussions. CRTC scholars only.

Credit 2 units.

Typical periods offered: Fall, Spring

CLNV 5140 MTPCI Research Seminar

Weekly seminar series are required for Postdoctoral Program and Career Development Program scholars for four semesters, one credit per semester. An important learning experience in research is the presentation and critical discussion of research ideas and projects at various points in their evolution. Seminars will alternate discussion of work in progress with critical reading of current clinical research in order to practice and enhance analysis and communication skills. Each scholar will formally present his or her own research in progress twice per year for feedback by peers and faculty from multiple disciplines. In addition to presenting their own work in oral and written form for peer and faculty evaluation, scholars will formally review the written proposals of their peers in a way that emulates the duties of a member of an NIH study section. This formal research evaluation exercise is a highly successful element of other clinical training instruction at Washington University. The Program Director and Co-Directors will lead a weekly seminar with participation of other core faculty. The weekly, small group, intensive discussions of research issues are one of the most valuable aspects of the program, allowing scholars to learn in an active and participatory fashion. Open to CRTC Postdoctoral Program

Credit 1 unit.

Typical periods offered: Fall, Spring

CLNV 5150 Introduction to Statistics for Clinical Research

This is an introductory course in statistics with a focus on the use of statistical analysis in clinical research. It is taught using SPSS, statistical analysis software commonly used in clinical research. The course teaches basic statistical methods with which clinical researchers will have the facility to execute their own analyses.

Credit 3 units.

Typical periods offered: Fall

CLNV 5151 Intermediate Statistics for the Health Sciences

This course builds upon Introduction to Statistics for the Health Sciences and will focus on SPSS, Cox proportional hazards, generalized linear models, multiple linear models, ANOVA, repeated measures, regression, applied modeling, 2X2, ROC curves, checking assumptions

and regression diagnostics. Completion of this course will enable clinical investigators to work independently with their own data and run their own analyses. Content will include data sets with applied exercises, interpreting output, lab assignments and a midterm and final exam. Course-master is Mark Walker, PhD, and Instructor is Brian Waterman, MPH.

Credit 3 units

Typical periods offered: Spring

CLNV 5160 Grantsmanship

Scholars will learn how to 1) develop research and career development grant proposals that incorporate well-formulated hypotheses, rationales, specific objectives and long-range research goals; 2) organize and present sound research and career development plans that accurately reflect the ideas and directions of the proposed research activities; and 3) avoid many common grant-writing mistakes. Scholars will also learn about the peer review process for grant evaluations and will participate in a mock NIH review exercise (study section) at the end of the semester. Though it is not required, scholars will get maximum benefits from the class if they are working on grant proposals.

Typical periods offered: Fall

CLNV 5170 Scientific Writing and Publishing

The objective of this course is to teach the proper techniques of writing and publishing a biomedical manuscript. Writing a working title and structured abstract as well as hand drawing of figures and tables is covered. Publishing strategies are also discussed.

Credit 2 units.

Typical periods offered: Spring

CLNV 5220 Genomics in Medicine I

This course introduces principles of genomics in medicine as they apply to clinical research and provides a practical background in molecular biology and genetics. Students will be provided with an introduction to genomic research and applications of genomic technologies in the research environment and an understanding of the clinical application of genetic/genomic knowledge. Critical thinking and scientific/analytic competencies are emphasized through weekly lectures by renowned faculty. Reflection papers are required. Prior clinical research experience is helpful but not required. Course options include face-to-face, hybrid, and online.

Typical periods offered: Fall

CLNV 5221 Genomics in Medicine II

This course will introduce fellows-in-training and future physician scientists to the core principles of scientific investigation. This unique three-week intensive format will combine theoretical knowledge with practical, hands-on applications to provide students with an understanding of common research approaches used in current scientific endeavors. Course lectures will highlight the following areas: molecular medicine; biospecimens and tissue banking; gene expression; immunoassays and controls; immunolocalization techniques; flow cytometry and cell sorting; cell signaling; sequencing technologies; microarray and related technologies; proteomics and mass spectroscopy; animal models; and bioinformatics. The lectures will be complemented by hands-on laboratory experiences in ELISA, DNA Extraction & PCR, Electrophoresis, Western Blot, and Basic Lab Animal Handling.

Credit 1 unit.

Typical periods offered: Spring



CLNV 5230 Introduction to Dissemination and Implementation Science

Upon successfully completing this class, scholars will be able to: Describe the need for dissemination and implementation research, compare theories and frameworks in the field, select the appropriate designs, strategies, outcomes, and measures for implementation studies. Scholars will also: Understand the importance and language of D&I basic science, explore the theories and frameworks that are commonly used in D&I research and practice, describe the importance of context at multiple levels in D&I science, distinguish between implementation strategies and outcomes from those in efficacy and effectiveness research, describe various study designs, methods, and measures that support D&I science, understand D&I methods and challenges across various settings and populations, recognize opportunities to apply D&I science to intervention development and evaluation, and understand how D&I science can further your research/practice plans and career.

Credit 3 units.

Typical periods offered: Fall

CLNV 5240 Implementation Science: Measures, Metric and Methods

This course will address key methodological approaches in implementation science, focusing on methods with particular or distinctive relevance to implementation research. The course begins with an introduction to concepts of causality and tools for rendering causal relationships, and suggests that these tools are useful for scientific insights into context, adaptation, heterogeneity, external validity and other issues salient in implementation research. We will cover how to capture and represent strategies, the concept of implementation outcomes and how they can be measured. The course will cover methods relevant for approaches at the organizational, practice, or regional level, based on cluster-level considerations about sampling, measurement and analysis. Subsequently, we will apply a causal lens to examine some prominent issues in measurement including concepts such as sustainability, context and other concepts. Finally, the course will close a look at present methods of appraising research and rating evidence, such as GRADE and problematize these methods for implementation research, and suggest future directions. Credit 3 units.

Typical periods offered: Spring

CLNV 5260 Bench Fundamentals for Translational Research

This course will introduce fellows-in-training and future physician scientists to the core principles of scientific investigation. This unique three-week intensive format will combine the theoretical knowledge with practical, hands-on application to provide students with an understanding of common and new and innovative research approaches used in current scientific endeavors. Course lectures will highlight the following areas: molecular medicine; biospecimens and tissue banking; gene expression; immunoassays and controls; immunolocalization techniques; flow cytometry and cell sorting; cell signaling; sequencing technologies; microarray and related technologies; proteomics and mass spectroscopy; animal models and bioinformatics. The lectures will be complemented by hands-on laboratory experiences in tissue culture, protein extraction and blot, cell signaling and ELISA, PCR and electrophoresis; and plasmid purification. The first two weeks of the course introduce course content via online lectures; the third week requires face-to-face lab work. Credit 3 units.

Typical periods offered: Summer

CLNV 5420 Designing for Dissemination, Implementation & Sustainability: How to Maximize Impact and Equity

This course will introduce students to modern concepts in design thinking and how they affect dissemination, implementation, and sustainability of health interventions in clinical and public health translational research practice. This course will provide students with methods in all stages of the design thinking process: 1) empathize; 2) define; 3) ideate; 4) prototype; and 5) test. The goal of this approach is to ensure that the products of research (interventions, materials, and findings) are developed in ways that match well with the needs, resources, workflows, and contextual characteristics of the target audience and setting to maximize impact and equity. Credit 3 units.

Typical periods offered: Fall

CLNV 5440 Independent Study

Active participation in research and/or scholarly activities with program faculty. A written plan of study agreed upon by faculty and student. Permission of faculty advisor required.

Credit 3 units.

Typical periods offered: Fall, Spring, Summer

CLNV 5882 Analysis of Clinical Data

Analysis of Clinical Data is a one-credit, online course consisting of different teaching modules. Course material is the same for short-term and intensive research core trainees. The goal of the course is to teach basic biostatistical analysis using clinical examples. Specifically, this course will cover: populations and samples; scales of measurement; variables; frequency distributions; central tendency; variability, probability, normal distribution, and sampling distribution; introduction to hypothesis testing and sample size; one-sample t-test, independent samples t-test, paired t-test; one-way ANOVA; nonparametric statistical procedures; post-hoc testing; correlation and regression; logistic regression; calculation of survival curves/life tables, and Cox-regression. Open to CRTC Predoctoral Program scholars only. Credit 1 unit.

Typical periods offered: Summer

CLNV 5890 Advanced Methods for Clinical and Outcomes Research

This course focuses on the application of advanced epidemiologic principles and outcomes research as applied to clinical research. Students study the tools used in clinical research, in clinical issues, and in understanding the medical literature concerning these issues, which are crucial for making informed decisions in the care of patients. Critical thinking and scientific/analytic competencies are emphasized throughout the course.

Credit 3 units.

Typical periods offered: Spring

CLNV 7883 Master's Continuing Student Status

Full-time graduate research Credit 0 units.

Typical periods offered: Fall, Spring, Summer