Clinical Investigation

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Courses


M17 CLNV 503 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 course work and seminars. Open to CRTC Predoctoral Program scholars only. Credit 1 unit.

M17 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.

M17 CLNV 5110 MTPCI Mentored Independent Research
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 course work and seminars. Open to CRTC Postdoctoral Program scholars only. Credit variable, maximum 4 units.

M17 CLNV 513 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, research-in-progress discussions, and reading journal discussions. CRTC scholars only. Credit 3 units.

M17 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 their 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 research 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 scholars only. Credit 1 unit.

M17 CLNV 515 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.

M17 CLNV 518 Drug and Device Development
This course will provide an overview of the commercial development pathways for both pharmaceuticals and medical devices, from inception to market. Through lectures and discussions, students will gain an appreciation for the role...
clinical study programs play in the broader scope of product
development. Class topics will include preclinical, clinical,
regulatory, and marketing factors which influence discovery and
development of new medical products.

Same as U80 CRM 518
Credit 3 units.

M17 CLNV 520 Entrepreneurship for Biomedicine I
Today's biomedical research trainees have the opportunity
to pursue multiple career paths within academic, industry,
nonprofit, and entrepreneurial settings. In addition to scientific
and technical expertise, today's trainees need additional skills in
innovation and entrepreneurship (I&E) to take advantage of this
opportunity. This course is designed to teach these skills. This
course consists of seven "nanocourses" focused on different
aspects of the entrepreneurial process. Throughout the course,
trainees will work to identify an innovation and assess a new
academic, entrepreneurial, or nonprofit venture to bring that
innovation to market. Nanocourses are taught by successful
real-world entrepreneurs and experts in their fields. The primary
instructional methods are via video and hands-on learning
experiences, with some supplementary reading. To succeed in
this class, students should be prepared to work with their peers
and coursemasters using online communication tools both inside
and outside Canvas.
Credit 1 unit.

M17 CLNV 522 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.

M17 CLNV 524 Intermediate Statistics for the Health
Sciences
This course builds upon Introduction to Statistics for Clinical
Research (M17-522) 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 director is Mark Walker, PhD, and instructor is
Brian Waterman, MPH. Prerequisite: M17-522.
Credit 3 units.

M17 CLNV 528 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.

Credit 2 units.

M17 CLNV 529 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.

M17 CLNV 532 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.
Credit 1 unit.

M17 CLNV 533 Genomics in Medicine II
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. Students
may enroll in this course even if they have not taken Genomics
in Medicine I (M17-532). Prior clinical research experience is
helpful but not required. Course options include face-to-face,
hybrid and online.
Credit 1 unit.

M17 CLNV 540 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.
M17 CLNV 541 Methods, Metrics and Measures for Dissemination and Implementation Research

Despite the unequivocal successes of biomedical research over the last generation, the use of evidence-based clinical interventions in routine public health and clinical practice remains far from optimal. Today, Americans receive approximately half of indicated medical care (and much unindicated care as well). As a result, even though the past 30 years have yielded unprecedented gains in clinical and medical sciences, the health of Americans lags behind that of other industrialized countries. Globally, the proportion of morbidity and mortality due to available (and affordable) but unused clinical interventions is even larger. Dissemination & Implementation (D&I) research is an emerging area of scientific inquiry with a growing body of distinctive perspectives and methods that seeks to tackle this gap. This course focuses on approaches of particular or distinctive relevance to implementation research. Given that implementation issues often occur at an organizational, practice, or regional level, knowledge of concepts involving multi-stage sampling, attendant design effects, quantification of within- and between-cluster correlation, and cluster-level randomization is crucial. In addition, many emerging concepts in implementation research — including context, adaptation, strategies and outcomes — are now accompanied by advancement in their conceptualization and measurement. This course introduces the foundational methods of measurement development (e.g., latent class analysis, criterion and construct validity) as well as important recent publications in this area (e.g., the Program Sustainability Assessment Tool). The final part of this course will focus on the use and appraisal of data taken from health systems, including administrative databases and electronic medical records, to assess implementation behaviors and outcomes. Each of the areas covered in this course will offer practical knowledge and skills for advancing implementation research.
Credit 3 units.

M17 CLNV 588 Epidemiology for Clinical Research

The purpose of this course is to provide an understanding of the use of epidemiological concepts and methods in clinical research. Two primary foci are included: 1) common applications of epidemiologic principles and analytic tools in evaluating clinical research questions; and 2) student development of skills to review and interpret the medical literature and utilize publicly available datasets to address clinical research questions.
Same as M88 AHBR 588
Credit 3 units.

M17 CLNV 589 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. Prerequisite: M17-513 Designing Outcomes for Clinical Research
Credit 3 units.