

# Clinical Investigation

The Master of Science in Clinical Investigation (MSCI) and the Certificate in Clinical Investigation (CI) are programs for young investigators committed to pursuing academic careers in clinical research. The unique MSCI degree combines didactic course work with mentored research and career development opportunities, and it provides students with the knowledge and tools needed to excel in the areas of clinical investigation most relevant to their careers. The CI certificate is made up of the core MSCI didactic course work in study design, research implementation, statistical approaches, responsible conduct of research, scientific communication and literature critique, leadership, and community engagement. Clinical investigation programs offered through the Washington University School of Medicine are sponsored by the Clinical Research Training Center and the Institute of Clinical and Translational Sciences.

Students in the 33-credit MSCI program will do the following:

- Engage in high-quality didactic courses (refer to the MSCI course list) with mentored research and a weekly multidisciplinary seminar to meet the needs of clinicians seeking training in clinical research
- Gain knowledge in the core competencies of clinical research and investigation, such as study design, research implementation, statistical approaches, responsible conduct of research, community engagement, scientific communication and literature critique, and leadership
- Pursue one of four concentrations: Translational Medicine, Genetics/Genomics, Clinical Investigation, or Dissemination and Implementation, with each concentration providing focused training that is tailored specifically to a student's interest within clinical and translational research
- Attend a weekly multidisciplinary seminar to learn about alternative research designs and methods through the discussion and presentation of peers' research and to obtain key feedback from senior faculty and peers with expertise in their fields
- Attend monthly career development sessions to learn best practices in areas critical to success in clinical research, including grant writing, data management, intellectual property management, budgeting, ethics and other areas
- Complete a thesis requirement consisting of a manuscript of original clinical research submitted for publication
- Participate in a formal, structured mentorship program that offers an opportunity to work alongside faculty renowned for their innovative clinical research and teaching experience

## Location

Core courses are held on the School of Medicine campus after 4:00 p.m. to accommodate working professionals and full-time students participating in mentored research activities.

## Additional Information

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Program Manager – Curriculum and Evaluation

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### David Warren, MD, MPH

Program Director

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### Dominic Reeds, MD

Program Director

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Washington University School of Medicine

Master of Science in Clinical Investigation Program

Clinical Research Training Center

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## Degrees & Offerings

- Master of Science in Clinical Investigation
- Graduate Certificate in Clinical Investigation

## Research

While in the program, scholars conduct their own clinical research projects. These projects must receive Institutional Review Board approval, and they need to involve either patients, human tissue, human cell lines or clinical data. The resulting thesis manuscript cannot be a review article, case report or case series. Multidisciplinary mentors and leaders guide research projects and encourage career development activities. Research in progress is presented at multidisciplinary seminar sessions during which peer and mentor feedback is received. Program graduates have published more than 740 peer-reviewed manuscripts; secured more than 100 federal, state and privately sponsored grants; and presented at more than 1,000 conferences, symposia and meetings locally, nationally and internationally.

## Faculty

### Ana A. Baumann, PhD

Research Assistant Professor

Brown School of Social Work

### Stephanie Solomon Cargill, PhD

Adjunct Assistant Professor, Medicine

Department: Internal Medicine

### Patricia Cavazos-Rehg, PhD

Associate Professor

Department: Psychiatry

**Karen L. Dodson, MBA**

Manager, Professional Development  
Department: Office of the Associate Dean of Faculty Affairs

**Brian F. Gage, MD, MSc**

Professor of Medicine  
Department: Internal Medicine  
Division: General Medical Sciences

**Elvin Geng, MD, MPH**

Professor of Medicine  
Department: Internal Medicine  
Division: Infectious Diseases

**Dorina Kallogjeri, MD, MPH**

Research Statistician  
Department: Otolaryngology

**Jessica Mozersky, PhD**

Assistant Professor in Medicine  
Department: General Medical Sciences

**Jay F. Piccirillo, MD, FACS**

Professor of Otolaryngology  
Department: Otolaryngology

**Dominic Reeds, MD**

Assistant Professor of Medicine  
Department: Internal Medicine  
Division: Nutritional Science

**Carl Siekmann, MBA**

Adjunct Instructor  
Department: School of Continuing & Professional Studies, Clinical  
Research Management Program

**Peter Takes, PhD, RAC, FRAPS**

Adjunct Instructor  
Department: School of Continuing & Professional Studies, Clinical  
Research Management Program

**David K. Warren, MD, MPH**

Professor of Medicine  
Department: Internal Medicine  
Division: Infectious Diseases

## Courses

Visit online course listings to view offerings for M17 CLNV.

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### 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 coursework and seminars. Open to CRTC Predoctoral Program scholars only.  
Credit variable, maximum 6 units.

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### M17 CLNV 510 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.

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### 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. 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 variable, maximum 5 units.

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### 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, weekly problem sets, weekly reading assignments, outlining a research protocol, and a final exam.  
Credit 3 units.

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### 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 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 scholars only.

Credit 1 unit.

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#### **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.

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#### **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. UColl: OLI

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#### **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.

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#### **M17 CLNV 524 Intermediate Statistics for the Health Sciences**

This course builds upon Introduction to Statistics for the Health Sciences (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-master is Mark Walker, PhD, and Instructor is Brian Waterman, MPH. Prerequisite: M17-522

Credit 3 units.

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#### **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.

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#### **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.

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#### **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.

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#### **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.

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#### **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.

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#### **M17 CLNV 541 Implementation Science: Approaches in Local, Regional and Global Contexts**

This course will address key conceptual dimensions of implementation science in the setting of social, political and organizational constraints due to inadequate or uncertain investments in health. Such environments create distinctive needs for implementation of evidence-based interventions. These contexts are common in Lower-and-Middle Income countries, where human resources for health, health care infrastructure and investments in social protections are limited. However, limited, concentrated and racialized investments in public health are also characteristic in High-Income Countries, and lead to health disparities. In both cases, this structural setting shapes

the limitations in availability of evidence-based interventions for health, as well as the strategies needed to overcome those barriers. Specific topics in the course will touch on current global and regional distribution of disease burden, parallels in health systems in health systems in Low-and-Middle-Income countries and regions locally, global trends and efforts around use of evidence based treatments for major infectious diseases (e.g., HIV, TB and Malaria), rising burden of cardiovascular disease, as well as around Global Health, theories and frameworks on health disparities (e.g., post-colonial studies, Black scholarship). Topics will also include conceptualizing implementation strategies (and implementation outcomes) appropriate for this setting, and which are tailored for these constraints; study designs (e.g., stepped wedge, natural experiments) frequently employed in such settings; and the notion of preferences and personalization in public health delivered in such environments.

Credit 3 units.

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**M17 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.

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**M17 CLNV 5544 Developing and Evaluating Implementation Strategies in Health and Social Services**

Internationally, there is a substantial gap between the establishment of effective interventions and their delivery in routine practice. Implementation research has emerged as a means of addressing that gap. It is defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices" to improve the quality of service delivery in routine care settings (Eccles & Mittman, 2006). It includes the study of influences on professional and organizational behavior that impact implementation effectiveness. This course focuses on developing and evaluating implementation strategies or the methods and techniques that are used to enhance the adoption, implementation, sustainment, and scaling up of effective interventions. It is intended for graduate students, postdoctoral students, staff, and faculty in public health, social work, medicine, and other areas of health science who are interested in developing and/or testing strategies to promote improved implementation of effective health and social service interventions.

Same as S55 MPH 5554

Credit 3 units.

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**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.

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**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.