Clinical Investigation

The Master of Science in Clinical Investigation (MSCI) and 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 provides students with the knowledge and tools 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 (https://crtc.wustl.edu) and the Institute of Clinical and Translational Sciences (http://icts.wustl.edu).

Students in the 33-credit MSCI program:

- Engage in high-quality didactic courses (refer to the MSCI course list (https://crtc.wustl.edu/courses/class-list/msci-courses)) 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.
- May pursue one of three concentrations: Translational Medicine, Genetics/Genomics, or Clinical Investigation (https://crtc.wustl.edu/msci-concentrations). Each concentration provides focused training that is tailored specifically to a student's interest within clinical and translational research.
- Attend a weekly, multidisciplinary seminar in order to learn about alternative research designs and methods through the discussion and presentation of peers' research and obtain key feedback from senior faculty and peers with expertise in their field.
- 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 (https://crtc.wustl.edu/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

Suzie Fragale
Program Coordinator – Curriculum and Evaluation
Phone: 314-747-8936
Email: fragale@wustl.edu

David Warren, MD, MPH
Program Director
Email: dwarren@wustl.edu

Washington University School of Medicine
Master of Science in Clinical Investigation Program
Clinical Research Training Center
660 South Euclid Avenue, CB 8051
St. Louis, MO 63110

Email: crtcmsci@email.wustl.edu
Website: https://crtc.wustl.edu

Degrees & Requirements

Master of Science in Clinical Investigation

Program Requirements

Didactic Course Work

All MSCI scholars must complete 33-credit hours of didactic course work, including 16 core credits, 4 credits of MTPCI Research Seminar, at least 6 credits of electives, and variable credits of mentored independent research. For additional information about the specific courses required for each of the concentrations, please visit the MSCI Concentrations webpage (https://crtc.wustl.edu/msci-concentrations). Core courses include:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLNV 513</td>
<td>Designing Outcomes and Clinical Research</td>
<td>3</td>
</tr>
<tr>
<td>or CLNV 588</td>
<td>Epidemiology for Clinical Research</td>
<td></td>
</tr>
<tr>
<td>CLNV 510</td>
<td>Ethical and Legal Issues in Clinical Research</td>
<td>2</td>
</tr>
<tr>
<td>CLNV 522</td>
<td>Introduction to Statistics for Clinical Research</td>
<td>3</td>
</tr>
<tr>
<td>M17 CLNV 590</td>
<td>Intermediate Methods for Clinical and Outcomes Research</td>
<td>3</td>
</tr>
<tr>
<td>CLNV 524</td>
<td>Intermediate Statistics for the Health Sciences</td>
<td>3</td>
</tr>
<tr>
<td>CLNV 528</td>
<td>Grantsmanship</td>
<td>2</td>
</tr>
</tbody>
</table>
Thesis

Scholars will form a thesis committee consisting of three faculty members and will meet with them at least twice per year. The thesis committee should include the scholar's primary mentor, the MSCI program director, and a third faculty member in a closely related research field. The committee meetings will consist of reviewing the scholar's plan for completing and publishing a research project and manuscript. Scholars will return signed Mentorship Committee forms to the CRTC by December 1 and May 1. The final approval meeting will consist of a formal 15-minute presentation of the research followed by the committee's discussion of the manuscript. Visit the Thesis Requirement webpage for more detail. The thesis must be based on original human research conducted during the period of pursuit of the degree. An alternate entrepreneurial thesis option is also available.

CRTC Seminar

Scholars are required to attend the weekly CRTC Seminar (currently held on Tuesday afternoons) during the fall and spring semesters (mid-August through May). During their first and second years of the program, scholars are required to present research-in-progress once each year. Feedback will be provided by the directors, mentors and peers in attendance. The second week of each month will be dedicated to career development topics. During these seminars, speakers will be invited from outside the MSCI program to present.

Mentors

Developing a successful clinical and translational research career requires strong relationships with mentors and a research team. Each scholar must have a program-approved primary research mentor. This mentor will be the scholar's main source of research supervision and career development. It is expected that scholars will meet weekly with their mentor and that the mentor will be available for consultation and support concerning the scholar's current projects and future progress. The mentor is expected to provide formal feedback to the scholar at least semiannually. In addition to the scholar's research mentor, the MSCI program director will serve as a mentor to the scholar to further assist in each scholar's career development during the program.

Responsible Conduct of Research (RCR)

Scholars are required to complete the Ethical and Legal Issues in Clinical Research (CLNV 510) course during their time in the program as part of their training in the Responsible Conduct of Research.

IRB Approvals

Scholars are required to obtain IRB approval for all research conducted as part of their MSCI degree and to provide documentation of current IRB approvals for their research project(s) to the MSCI program.

Individual Development Plans

MSCI scholars must develop an Individual Development Plan in consultation with their mentors and must submit the plan by July 1 each year. The plan should include individual development goals for the next 1-5 years, career objectives for each goal, research activities/projects that will assist the scholar in meeting the objectives, and an overview of the courses, workshops and other educational/training activities that the scholar plans to pursue. For each objective, the scholar should indicate what individual products (degrees, publications, presentations, grants, etc.) are expected. A timeline should be constructed to display the individual objectives, educational activities, research activities and products.

Career Development Retreat

All MSCI scholars are required to attend the annual retreat hosted by the CRTC. During the late-afternoon event, speakers will highlight topics of relevance to scholars’ career development and research.

Research Training Symposium and Poster Session

In October of each year, the Washington University School of Medicine hosts a schoolwide, half-day Research Training Symposium and Poster session. All MSCI scholars are strongly encouraged to submit an abstract and present a poster at the symposium each year of their appointments. Scholars are given the option to have their research considered for an oral presentation.

Program Evaluation

Scholars are expected to complete required program evaluations twice per year. These evaluations are administered online and are mandatory for all scholars. Scholars are also required to complete an exit interview one month prior to completing their degree.

Eligibility

Level of Education

MSCI candidates must either be enrolled in a pre- or postdoctoral mentored research program at Washington University School of Medicine or hold a postdoctoral appointment in health science at Washington University or one of the ICTS affiliates.

Citizenship

Eligible applicants must be citizens or noncitizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence and have in their possession an
Alien Registration Receipt Card (I-151 or I-551) or other legal verification of admission for permanent residence. Individuals on temporary or student visas are eligible provided that they hold a valid U.S. visa and a postdoctoral appointment at Washington University or one of the ICTS affiliates. The MSCI program is unable to sponsor visas. Typically, students who desire to enter the program obtain a visa sponsored through their research department.

**Research Project**

All applicants must be conducting clinical and translational research. Clinical research is defined as patient-oriented research, that is, research conducted with human subjects or on material of human origin such as tissues, specimens and cognitive phenomena, for which an investigator or colleague directly interacts with human subjects.

**Mentor**

Applicants must have an established relationship with a senior faculty member prior to beginning the MSCI program. Applicants should look for mentors that match their research interests. They should contact each mentor they are interested in working with directly, stating their interest in the mentor's research and the applicant's desire to work with them. Suggested mentors can be found on our website. If applicants are having problems finding a mentor, they should contact us.

**Graduate Certificate in Clinical Investigation**

The Graduate Certificate in Clinical Investigation (CI) is a 16-credit certificate program for young investigators committed to pursuing academic careers in clinical research.

- Students will gain knowledge in the core competencies of clinical research and investigation such as study design, research implementation, statistical approaches, responsible conduct of research, scientific communication and literature critique, leadership, and community engagement.
- On average, scholars complete the certificate requirements within one to two years. All course work must be successfully completed within five years from the start of the first course. Credits cannot be transferred into the CI program.
- The evening course format allows for full- or part-time enrollment that can accommodate clinical schedules at any point in a career.
- Three different tracks have been developed for the certificate: Clinical Investigation, Translational Medicine, Genetics/Genomics.

**Academic Policies**

Academic policies for the MSCI and graduate certificate programs can be found in the MSCI Academic Policies Handbook (PDF).

**Research**

While in the program, scholars conduct their own clinical research projects. The research project must receive IRB approval and needs 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 where peer and mentor feedback is received. Program graduates have published over 740 peer-reviewed manuscripts, secured over 100 federal, state, and privately sponsored grants, and presented at over 1,000 conferences, symposia, and meetings locally, nationally and internationally.

**Faculty**

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

Jane Garbutt, MB, ChB
Professor of Medicine
Department: Internal Medicine & Pediatrics
Division: General Medical Sciences

Ramaswamy Govindan, MD
Professor of Medicine
Department: Internal Medicine
Division: Oncology

Dorina Kallogjeri, MD, MPH
Research Statistician
Department: Otolaryngology

Albert Lai, PhD
Assistant Professor
Department: General Medical Sciences
Division: Institute for Informatics

Jessica Mozersky, PhD, MBE
Assistant Professor in Medicine
Department: Internal Medicine
The goal of this course is to prepare clinical researchers to identify ethical and regulatory issues in clinical research. The principal focus is on preparing researchers to critically evaluate PIs' proposals, 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 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.

By the end of the course, participants will be able to:
- identify major ethical concerns in the conduct of clinical research, including situational factors that may give rise to them, to identify ethics and compliance resources, and to foster ethical problem-solving skills.
- 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.

M17 CLNV 510 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 course work and seminars. Open to CRTA 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, weekly problem sets, weekly reading assignments, outlining a research protocol, and a final exam.
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 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 519 Industry Partnering: Collaborations in Translational Research
Innovative new products are the life blood of the biopharmaceutical industry. In the U.S., most discovery research originates at the university level and is transferred via licensing agreements to industry partners or to start-up biotech companies for final development and commercialization. The process of moving this innovation from the lab to industry and then to the patient is the focus of this course. The course examines the market for intellectual property that exists between academic institutions and the private sector and explores commercialization of translational research through collaboration with industry partners. In addition to studying the complex relationship between science and business, the course employs a case study methodology to illustrate specific examples of the translational process from lab to marketed product. Same as U80 CRM 529. Credit 3 units.

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 create a focused research plan that incorporates well-formulated hypotheses, rationales, specific objectives and long-range research goals; organize and present a sound research plan that accurately reflects the ideas and directions of the proposed research activities; develop and justify a budget for the proposed research activities; avoid many common grant-writing mistakes; discuss the peer review process in grant evaluation and formulate a grant proposal that is maximally compatible with that process. Students enrolled in this course should identify a grant to actively work on during the semester. 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 5302 Introduction to Biomedical Informatics I: Foundations
This survey course provides an overview of the theories and methods that comprise the field of biomedical informatics. Topics to be covered include: 1) information architecture as applied to the biomedical computing domain; 2) data and interoperability standards; 3) biological, clinical, and population health relevant data analytics; 4) health care information systems; 5) human factors and cognitive science; 6) evaluation of biomedical computing applications; and 7) ethical, legal, and social implications of technology solutions as applied to the field of biomedicine. The course will consist of both didactic lectures as well as experiential learning opportunities including "hands on" laboratory sessions and journal club style discussion. The course will culminate with a capstone project requiring the in-depth examination, critique and presentation of a student-selected topic related to the broad field of biomedical informatics. Biomedical Informatics I is designed primarily for individuals with a background in the health and/or life sciences and who have completed a course in introductory statistics (e.g., Math 1011). No assumptions are made about computer science or clinical background; however, some experience with computers and a high-level familiarity with health care will be useful. This course does not require any programming knowledge, and it will not teach students how to program. Credit 3 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 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 Intermediate 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: Epidemiology for Clinical Research or M17-513 Designing Outcomes and Clinical Research. Same as M88 AHBR 589 Credit 3 units.