Master of Science in Clinical Investigation
Student Handbook
2015-2016
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Revised: June 30, 2015
I. MS in Clinical Investigation Program: Overview

Mission
The MS in Clinical Investigation degree program provides classroom and mentored research experience in clinical research, preparing its trainees for careers in clinical investigation, both in academic medicine and the allied health sciences. The program prepares trainees to be competitive investigators capable of gaining extramural funding for their clinical research projects. The curriculum of the MSCI focuses on the theories, models, competencies, methods, and tools used by investigators who conduct bench-to-bedside and bedside-to-community translational research. Candidates for the MSCI degree will elect one of two areas of emphasis or "tracks". Track 1 emphasizes the inherited basis of human disease, mechanism-oriented clinical research, and bench-to-bedside translational research. The Track 2 emphasizes epidemiology, health services research, and bedside-to-community translational research. The program is designed to support a mentored research experience for fellows and junior faculty members at the University of Utah School of Medicine and other health science departments.

Credit Hours
Thirty credit hours will be required to graduate from the program. Students must take at least 20 credits of core and elective classroom courses. In addition, students will enroll for credits for their mentored clinical research projects. The expected time to completion of the MSCI degree is two years.

Curriculum
The curriculum for the MSCI program begins in July with a six-week intensive introductory session. Students in both tracks take a group of common core courses in epidemiology, data management, bioethics, biostatistics, and genetics. After completing the summer session, students participate in additional core and elective courses in fall and spring semesters. Our courses are described under the School of Medicine Clinical Research Center (MDCRC) heading in the University of Utah Catalog. The majority of fall and spring classes begin at 5:30 p.m. to reduce time conflicts with clinical responsibilities. Each Clinical Investigation student may tailor his or her program of study to fit individual research interests and goals, and may include courses offered by other departments with complementary curricula, e.g. Human Genetics, Oncological Sciences, Biomedical Informatics, or Public Health.
Supervisory Committee

A student starting the program will identify a primary research mentor to become the supervisory committee chair. In most cases, the mentor is from the student's department or area of clinical expertise. The student will select two additional faculty members to serve with their mentor on their MS degree supervisory committee. The committee chair must be tenure-line unless an exception has been filed with the graduate office. Additionally, the majority of a student’s supervisory committee must be tenure-line. The primary responsibility for monitoring the progress of students through the program will lie with the primary research mentor and the committee members. At least one member of the supervisory committee should be a faculty member with expertise in research methodology, usually chosen from the MSCI core faculty.

Research Project

The Master's program is intended to train individuals intending to pursue careers as independent clinical investigators and the preferred culminating project of the mentored clinical research experience may be the preparation and submission of an NIH career development application (e.g. K23, K08) or an equivalent federal or foundation career development grant. The second option for the format of the research project is a manuscript to be submitted to a peer-reviewed research journal. In the semester that the student graduates, he or she will present a public seminar about the project and submit a written MS project report.

II. Faculty

Current MSCI core faculty who participate in the didactic teaching for the MSCI degree include the following:

<table>
<thead>
<tr>
<th>Kristina Allen-Brady</th>
<th>Research Assistant Professor</th>
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<td>Division of Genetic Epidemiology</td>
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- B.A. in Chemistry with a Minor in Mathematics, University of Utah
- M.P.T. in Physical Therapy, University of Utah
- M.S.P.H. in Public Health, University of Utah
- Ph.D. in Genetic Epidemiology, University of Utah

Research interests: Underlying genetic causes of chronic diseases

Teaches: Introduction to Genetic Epidemiology
Mary Anne Berzins  
*Assistant Vice President of Human Resources*  
Teaches: Team Communication and Collaboration for Translational Research

Joseph Biskupiak  
*Research Associate Professor*  
Department of Pharmacotherapy, College of Pharmacy  
B.S. in Chemistry, University of Connecticut  
M.B.A., Seattle University  
Ph.D. in Medicinal Chemistry, University of Utah  
Research interests: health economics, disease management and the U.S. Healthcare system  
Teaches: Methods in Comparative Effectiveness Research

Kristina Callis-Duffin  
*Assistant Professor*  
Department of Dermatology  
B.S. in Biomedical Sciences, Montana State University  
M.D., University of Washington  
M.S. in Clinical Investigation, University of Utah  
Research Interests: medical co-morbidities of psoriasis, clinical trials of psoriasis therapeutics, and psoriasis outcomes measures  
Teaches: Survey Methods

T. Charles Casper  
*Assistant Professor*  
Pediatric Critical Care  
B.S. in Mathematics, University of Utah  
M.Stat in Mathematical Statistics, University of Utah  
Ph.D. in Statistics, University of Wisconsin  
Research interests: recurrent events, semi and nonparametric methods, survival analysis, group sequential methods, clinical trials methodology  
Teaches: Design Clinical Trials

Tom Greene  
*Professor*  
Department of Internal Medicine, Division of Epidemiology  
*Acting Chair*  
Department of Population Health Sciences  
B.S. in Mathematics and Psychology, University of Kentucky  
M.S. in Statistics, Cornell University  
Ph.D. in Statistics, Cornell University  
Research interests: statistical methods for randomized clinical trials, longitudinal data analysis, and the validation and use of surrogate endpoints  
Teaches: Design of Clinical Trials
Lynn Jorde  
*Chair & Professor*  
Department of Human Genetics  
B.A. in Anthropology, University of New Mexico  
M.S. in Biological Anthropology, University of New Mexico  
Ph.D. in Biological Anthropology (Human Genetics Specialty), University of New Mexico

**Teaches:** Genetics of Complex Diseases and Medical Genetics for Clinical Investigation

Richard Holubkov  
*Professor*  
Department of Pediatrics  
B.S. in Statistics, University of Chicago  
M.S. in Statistics, Carnegie-Melon University  
M.S. and Ph.D. in Biostatistics, University of Washington

**Research interests:** biostatistics focusing on the design, execution, and analysis of prospective interventional studies, with a focus on pediatrics and cardiology  
**Teaches:** Design of Clinical Trials

Bernie Lasalle  
*Clinical Instructor*  
Department of Biomedical Informatics  
B.S. in Biology, University of Utah

**Research interests:** clinical research data management, database design, clinical trials, data ethics, and biospecimen management  
**Teaches:** Data Management

Anthea Letsou  
*Professor*  
Department of Human Genetics  
B.A. in Biology, Harvard University  
Ph.D. in Human Genetics, Yale University  
Postdoctoral Fellow in Molecular Biology, Princeton University  
Postdoctoral Fellow in Biochemistry, University of Texas Southwestern Medical Center

**Teaches:** Molecular Medicine Research Seminar
Dean Li  
*Associate Professor of Medicine*  
Human Molecular Biology & Genetics Program, Eccles Institute of Human Genetics  
B.A., University of Chicago  
M.D., Washington University  
Ph.D., Washington University  

**Research interests:** molecular events in vascular development, devising strategies for the prevention and treatment of malignancies and obstructive vascular disease.  

**Teaches:** Utilization of Animal Models in the Development of Clinical Research Projects

Howard Mann  
*Professor*  
Department of Radiology  
M.B.B.Ch, University of Witwatersrand

Maureen Murtaugh  
*Associate Professor of Medicine*  
Department of Internal Medicine, Division of Epidemiology  
B.S. in Dietetics, Syracuse University  
Ph.D. in Nutrition, University of Connecticut  
Post Doc. Epidemiology, University of Minnesota

**Research interests:** the role of nutrition in development of chronic disease  

**Teaches:** Grant Writing

Richard Nelson  
*Research Assistant Professor*  
Department of Internal Medicine, Division of Epidemiology  
B.S. in Mathematics and Economics, Westminster College  
M.A. in Economics, University of Virginia  
Ph.D. in Economics, University of Virginia  
M.S. in Clinical Investigation, University of Utah

**Teaches:** Cost-Effectiveness Analysis
Brian Sauer
Research Assistant Professor
Department of Internal Medicine, Division of Epidemiology
B.S. in Psychology (Biological), University of Florida
Ph.D. in Pharmacy Health Care Administration (Pharmacoepidemiology), University of Florida
M.S. in Public Health Informatics, University of Utah

Research interests: health care quality and patient safety, medical informatics, pharmacoepidemiology, and quality of medication use
Teaches: Methods in Comparative Effectiveness Research

Lucy Savitz
Research Associate Professor
Department of Internal Medicine, Division of Epidemiology
B.S. in Finance, University of Denver
M.B.A., University of Denver
Ph.D. in Health Policy and Administration, University of North Carolina at Chapel Hill

Teaches: Health Services Research and Conducting Patient Centered, Community Engaged Research

Joshua Schiffman
Assistant Professor
Department of Pediatrics
B.S. in Psychology/Biology, Brown University
M.D., Brown University
M.S. in Clinical Investigation, University of Utah

Research interests: translating biological and genomic discoveries to clinical patients and cancer susceptibility in families, with a focus on the genomic changes necessary for cancer development
Teaches: Foundations in Personalized Health Care

Greg Stoddard
Adjunct Assistant Professor
Department of Internal Medicine, Division of Epidemiology
Department of Orthopedics
B.S. in Mathematics (Statistics Emphasis), University of Utah
M.B.A. in Business Administration, University of Phoenix
MPH in Public Health/Epidemiology, University of Utah

Research Interests: statistical methods in epidemiology
Teaches: Introduction to Biostatistics, Computer Practicum, Regression Models, and Biostatistics for Basic Science
Carol Sweeney
*Associate Professor of Medicine*
Department of Internal Medicine, Division of Epidemiology
Department of Medicine
B.A. in Biological Sciences, Wellesley College
M.S. in Environmental Health, University of Washington
Ph.D. in Epidemiology, University of Washington

**Research interests**: cancer epidemiology with specific interests in the role of common genetic variants in cancer susceptibility and survival, and in the epidemiology of cancer survivors

**Teaches**: Introduction to Epidemiology and Intermediate Epidemiology

James Tabery
*Assistant Professor*
Department of Philosophy
M.A. in Bioethics, University of Pittsburgh
Ph.D. in History and Philosophy of Science, University of Pittsburgh

**Research interests**: philosophy of science and applied ethics and intersection between those domains. Questions of causation and explanation in biology; applied ethics of ethical, legal, and social implications

**Teaches**: Bioethical Issues in Clinical Research

Kirk Thomas
*Research Associate Professor*
Department of Internal Medicine, Division of Hematology
B.A. in Biology, University of California
Ph.D. in Biology, University of Utah

**Teaches**: Utilization of Animal Models in the Development of Clinical Research Projects

Kevin Whitehead
*Associate Professor*
Division of Cardiology
B.S. in Medical Science, University of Alberta
M.D., University of Alberta

**Research interests**: developmental biology, vascular development, and adult congenital heart disease

**Teaches**: Utilization of Animal Models in the Development of Clinical Research Projects
Brandon Bellows  
*Research Assistant Professor*  
Department of Pharmacotherapy in the College of Pharmacy  
PharmD, University of Utah  
M.S. in Clinical Investigation, University of Utah

**Research Interests:** clinical outcomes and health economics (chronic diseases), decision analytic modeling and cost-effectiveness analysis, use and implementation of real-world studies and pharmaeconomics in population health decision making

**Teaches:** Cost-effectiveness Analysis and Cost-effectiveness Analysis, Independent Project

Catherine Sherwin  
*Research Assistant Professor*  
Division of Clinical Pharmacology & Clinical Trials Office  
B.N., Australian Catholic University  
B.Sc. (Hons), Lincoln University  
Ph.D. in Paediatric Clinical Pharmacology, University of Otago  
M.S. in Clinical Investigation, University of Utah

**Research Interests:** modeling and simulation (pharmacometrics), clinical pediatric pharmacology and toxicology, pharmacokinetics, pharmacogenomics, pharmacodynamics, optimal trial design, and clinical trial simulation

**Teaches:** Implementation of Clinical Trials for the Comparative Effectiveness Research Educational Program

Lenora Olson  
*Professor*  
Department of Pediatrics  
B.A. in Anthropology, University of New Mexico  
M.A. in Anthropology, University of New Mexico  
Ph.D. in Health Education and Promotion, University of Utah

**Research Interests:** prevention of injury and violence especially in the area of violence against women and children

**Teaches:** Survey Methods
III. Expectations

The MS in Clinical Investigation faculty expect that you, as a student, will take responsibility for making progress in the program, for complying with policies of the degree program and of the Graduate School, and for communicating with the program faculty and with your supervisory committee.

Enrollment

In order to complete the MS program within two years, you should plan to complete about 15 credit hours per year. In the first year, for most students, the credits will be from course work. In the second year you will probably take fewer courses and will earn credits through mentored research project hours. MSCI students must be enrolled for a minimum of two credits every fall and spring semester from the time you are admitted until you graduate. Summer enrollment is optional, but some courses may only be offered in summer.

Class Attendance

The program recognizes that most MSCI students have significant clinical responsibilities. Accommodations for students with busy schedules include: offering classes in the evenings, making video recordings of many course lectures available for streaming, and web posting (on the Canvas course management site) of information needed to complete course assignments. Nonetheless, as a student you are expected to attend the majority of class meetings and to communicate in advance with the course instructor about class meetings that you will miss. Students enrolling in classes are expected to plan ahead with their clinical programs so the student’s clinical responsibilities do not conflict with attendance in class. At the discretion of the instructor, class participation may be a criterion for earning course credit and for your grade.

Participation in K-Club and Seminars

Interaction with your peers in the M.S. in Clinical Investigation program and with other researchers on campus forms part of your training in clinical investigation. While you are a student you will be expected to regularly participate in research seminars and/or research in progress (RIP) meetings. The Center for Clinical and Translational Sciences sponsors "K-Club", a discussion of junior faculty K-award proposals, meeting on the second Wednesday of the month at noon. The MSCI program also hosts their own Research in Progress seminar series, which occurs the 3rd Tuesday of each month. M.S. in Clinical Investigation students are encouraged to attend K-Club and required to present their MSCI research project at the MSCI RIP. Students will benefit from attending final project presentations by other students graduating from the program. Information about student final project presentations and other interdisciplinary and translational seminars will be distributed to the MSCI student email list and publicized on the CCTS education web site.
Student Progress Reviews
Each student-mentor team will be asked to complete an annual progress review at the end of every spring semester. The progress review will include a report on courses completed, progress on your MS final project, if applicable, any change to the semester you plan to graduate. The progress report will also include research activity including presentations, papers, and grants.

Course and program evaluations
The MSCI program conducts ongoing evaluation of its courses and of the program overall. These evaluations are required of us as a degree program approved by the Utah Board of Regents, and as a part of the NIH-supported Utah Center for Clinical and Translational Sciences (CCTS).

At the end of every semester, you will receive an evaluation form with a brief series of questions about the courses you were enrolled in. It is very important that students complete course evaluations. They evaluations are used to assess success of individual courses and as a basis for continuing to improve the curriculum to meet student needs. For instructors, results of course evaluations are provided to committees making recommendations about the faculty member’s retention, promotion, and tenure. Your responses are anonymous, but we are able to track whether the survey has been completed.

MSCI graduates can expect to be contacted around the time of graduation for exit interviews, and in later years, to obtain feedback on the overall value of the program on their research career progress.

Another way that the MSCI program measures of the success of the degree program is by tracking the research productivity of former students. We will obtain information about your research funding and publications through electronic means such as U of Utah Office of Sponsored Projects, NIH websites, PubMed, and Scopus. After you graduate we will occasionally get in touch to request your updated CV.

MS Project and Graduation Deadlines
The University of Utah requires that specific processes be followed as you proceed through forming a committee, defending a project, and graduating. There are deadlines for each of these steps. The MSCI program has prepared an outline of this process, and the program manager will help you navigate. Ultimately, though, it is the student’s responsibility to take the initiative and plan about a year ahead for completion of your MS project and graduation.
IV. Supervisory Committee and MS Project

MS Research Project

For the MS degree in Clinical Investigation culminating research project, one of two formats are acceptable, either 1) a career development or other grant application or 2) a manuscript reporting on a completed research project, to be submitted to a peer-reviewed journal. The choice of format depends on the student’s prior research experience and near-term research goals. A student who holds or is about to receive an appointment as an Instructor or Assistant Professor and has several prior research publications is in a good position to write and submit a career development grant application. For a fellow with few or no prior publications, the manuscript format is usually the right choice. For track 1 students who are concurrently earning a basic science PhD, the structure of the culminating activities for the MSCI will differ, as described under ‘Final Exam’.

The MSCI program emphasizes the development of strong clinical investigation skills based on a solid foundation in research methods. The MS project should demonstrate application of skills and competencies acquired through the core and elective coursework that the student completed in the program. Therefore it is recommended that the student complete one year of course work before defining the MS project and enrolling for research credit hours.

MSCI students are expected to start and complete the Master's research project while enrolled in the MSCI program. If the culminating project is a grant proposal, a proposal submitted before beginning the program is not an acceptable final project, nor is a grant proposal that will be submitted with someone other than the student as principal investigator. If the project is a manuscript, a research project substantially completed before being admitted to the MSCI program is not an acceptable master's project.

Supervisory Committee

The graduate school requires that a supervisory committee for a master's degree consists of a minimum of three and maximum of five faculty members. The committee chair, and a majority of committee members, must be tenured or tenure-line faculty.

The student is responsible for identifying members for his or her supervisory committee who have subject matter and methodological expertise that suit the research project. At least one member of the supervisory committee should be a faculty member with expertise in research methodology, usually chosen from the MSCI core faculty. An iterative process is recommended, i.e. the student meets with prospective committee members to develop and refine a research project topic and methods, and then finalizes the committee membership. The student will complete the "MS Project Plan and Committee Form" and obtain signatures from the committee members. This form must be submitted and approved before a student can register for research credits. Additionally, upon submittal of this form, students will be required to sign-up to present their project at the MSCI RIP.
For track 1b students who are concurrently a basic science PhD, there will usually be some overlap between the membership of the MS committee and membership of the PhD committee. However, these do no need to be identical. For the MS in Clinical Investigation committee, students are strongly encouraged to include a clinician and a member of the MSCI core faculty.

The roles of the graduate committee members are described on the “Research Project and Graduation Process” form found on the MSCI website (“Useful Links,” page 15). The level of involvement will vary, but each committee member should, at minimum, 1) contribute to and approve the research design 2) review and provide significant feedback on the draft of the final project write-up, and 3) attend the final project presentation and participate in discussion. If the final project is a manuscript, in many cases the committee members will have a level of involvement that merits authorship.

**MS Project Defense**

Each student will defend his or her final project at a public seminar. The student is responsible for scheduling a date and time when all committee members can be present. The final project presentation must happen before the “non-thesis final exam deadline” of the semester that the student intends to graduate. A draft of the written report of the final project must be distributed to the committee members and the MSCI program a minimum of four weeks before the defense. At the oral defense, the student will present the project and respond to questions from the committee and other audience members. The committee may choose to excuse the audience for closed session questioning of the student and/or for internal committee discussion.

**Final Examination**

The Final Examination for the MS degree in Clinical Investigation, as required for the graduate school under M.S. degree non-thesis option, will include both the written report (i.e. the career development proposal or manuscript) and the oral defense. For track 1b students who are concurrently earning a clinical science PhD, the clinical rotation report will serve as the written portion of the final exam for the MS degree. The oral portion of the exam will take place at the same time as the student’s defense of his or her PhD.

The student will pass if the supervisory committee finds that the written and oral components demonstrate master’s-degree level skills in clinical and translational research. A paper copy of the final report must be submitted to the program with a title page. A sample of the title page can be found on the MSCI website (“Useful Links,” page 15).
VI. Useful Links

University of Utah Course Catalog
   All University courses are searchable by keyword in the electronic course catalog (http://catalog.utah.edu/).

University of Utah Schedule of Classes
   The schedule for all University of Utah courses for each semester is available from the U's "Class Catalog and Schedules" page (http://www.utah.edu/students/catalog.php).

Tuition and Student Accounts
   To view your tuition bill please log into Campus Information Systems (https://go.utah.edu/cas/login).
   Then click on the student tab and see finance.
   Click here to contact income accounting/tuition (http://fbs.admin.utah.edu/income/).

Employee Tuition Benefit
   University employees who are eligible for the 50% tuition benefit must fill out a form every semester to request the benefit.

MSCI Partial Tuition Scholarship
   Students in good standing in the MS in Clinical Investigation may apply for partial tuition scholarships for fall and spring semesters. See the policy (http://medicine.utah.edu/ccts/edu/msci/files/MSCI_Tuition_Scholarship_Policy.pdf) regarding eligibility and application (http://medicine.utah.edu/ccts/edu/msci/files/MSCI_Tuition_Scholarship_Application.pdf).

Registrar
   To register for classes please log into Campus Information Systems (https://go.utah.edu/cas/login).
   Then click on the "student" tab and see registration.
   Click here to contact the registrar office (http://registrar.utah.edu/).

U of U Student Handbook
   The University of Utah Student Handbook is the reference for University-wide policies pertaining to students (http://registrar.utah.edu/handbook/index.php).

Graduate School Catalog
   Policies that apply to all University of Utah graduate degrees are presented in the University of Utah Graduate School Catalog (https://gradschool.utah.edu/graduate-catalog/). All students are expected to reference the catalog for deadlines and answers to questions regarding policy.

Masters Calendar
   Deadlines to apply for and complete the requirements for graduation are established by the graduate school each semester and shown here: Masters calendar (http://gradschool.utah.edu/current-students/graduation-overview-for-masters-candidates/).
MSCI Website

General Website
The MSCI Web site is a great resource for MSCI information including semester class schedules, upcoming events and more.
Click here to visit our website (http://www.msci.utah.edu/).

K Club
For a list of K Club presenters, check our website (http://medicine.utah.edu/ccts/edu/msci/seminars.php).

MSCI Research in Progress
For a list of K Club presenters, check our website (http://medicine.utah.edu/ccts/edu/msci/seminars.php#rip).

MSCI Canvas Page
The MSCI Canvas page is a great resource for course syllabi, course recordings, K Club information and more. Please use your UNID and Password and log into your canvas portal (https://utah.instructure.com/).

MSCI Course Descriptions
Click here for the MSCI Course descriptions (http://catalog.utah.edu/).