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**Requirements for the MSCI Degree**

**Didactic Work:** Trainees must complete 35 hours of courses covering the essentials of study design, biostatistics, ethics, drug development and data analysis. It is expected that course work will comprise 20% of the trainee's time commitment. The course schedule is designed to maximize protected time for patient-oriented research.

**Mentored Research Apprenticeship:** The core of the MSCI Program will be the completion of a mentored research project. The research must be patient-oriented and involve direct measurements on patient-derived samples or the use of investigational therapeutic or diagnostic techniques. The mentor must be an established physician-scientist with experience in patient-oriented research. Use of the Vanderbilt University General Clinical Research Center will be encouraged. The research project will account for 80% of the trainee's commitment to the program.

**Career Path Development:** A monthly seminar series, Clinical Scientist Career Seminars, permits trainees to meet successful patient-oriented researchers. Topics of discussion will include academic “rules of the road,” time management, promotion/tenure issues, grants management, and overall program evaluation. Trainees will also hone their scientific communication skills.

**Final Project Submission:** The trainee will submit a manuscript to a peer-reviewed journal, provide a completed proposal for a federal or major foundation grant, or develop a Master's thesis based on their research project. Completion of the thesis requirement will be evaluated by the MSCI Promotions Committee.

**Core courses comprise 35 credit hours; a minimum of 35 credit hours are required for graduation. Trainees may elect to enroll in one or more of the selected elective courses to further support their research project.**
This course will teach practical, modern biostatistical skills and help the student to become multilingual regarding statistical software. Students will use several statistical software packages to learn data analysis methods for reproducible research using actual clinical research data sets. Students will also learn about statistical power and sample size calculations using the software PS and nQuery Advisor. An emphasis will be placed on performing statistical analyses and interpreting output. Commonly used statistical methods will be explained as well as the techniques that experienced biostatisticians use to analyze data.

Texts & Readings:


Software:

R
SPSS
STATA
PS
nQuery Advisor
Biostatistics II

Course Director: Ayumi Shintani, PhD, MPH
Spring [4 hours credit] Shintani

Fundamental biostatistical concepts related to multivariable analyses in existence of confounding and effect modification. Topics include Student's t-test, one-way ANOVA, linear, binary logistic, proportional odds logistic, Cox proportional-hazard regressions with emphasis in checking model assumptions. Basic concepts on repeated measures analysis including a mixed-effect and GEE regression models. Proper strategies for developing reliable multivariable models in prognostic-diagnostic research, randomized controlled trial and observational study for causation.

Texts & Readings:


Prerequisite, MSCI Biostatistics I 524-5009 and Epidemiology I.
The Case Studies I course is designed to utilize a studio process to enrich trainee research. Studios are structured, dynamic sessions which bring together relevant research experts with the purpose of enhancing research quality, improving funding success, fostering advances in clinical practice and improvements in patient health, increasing publications and generating new hypotheses. Participants include 2-6 experienced faculty, your mentor, your MSCI peers, and the MSCI program directors.

You choose the most appropriate studio depending on the stage of your research: hypothesis generation, study design, implementation, analysis and interpretation, translation, or manuscript development. Presentations should be conducted as if presenting at a research conference.

Attendance at peers’ studios is expected as it will foster critical thinking from an interdisciplinary approach, collegiality, and collaboration.
The Case Studies II course provides an opportunity to present and discuss the progress and results of trainees’ primary MSCI projects. In accomplishing this goal, the course utilizes a studio process and/or presentation format.

You choose the most appropriate format depending on the stage of your research: presentation, manuscript studio, data analysis studio, or grant review studio. Studios will be conducted in the same manner as in Case Studies I. Presentations should be conducted as if presenting at a research conference.

Attendance at peers’ studios is expected as it will foster critical thinking from an interdisciplinary approach, collegiality, and collaboration.
Clinical Scientist Career Seminars

Course Directors: T. Alp Ikizler, MD
Fall and Spring [1 hour credit] Ikizler

Topics of discussion will include academic “rules of the road,” time management, promotion/tenure issues, grants management, and overall program evaluation. Trainees will hone their scientific communication skills through an annual presentation at this forum.

Although you engage in the seminars throughout your MSCI matriculation, you only receive credit once.
Clinical Trials

Course Director: Yu Shyr, PhD
Fall [3 hours credit] Shyr

Design and data analysis for clinical trials in biomedical research. Primary topics include specification of study objectives, design options, ethical guidelines, randomization, blinding, sample size determination and power analysis, interim monitoring and data analysis appropriate for parallel, crossover, nested, factorial and group allocation designs. Other topics include role of FDA in the drug approval process, adaptive trial designs, non-inferiority trials and bio-equivalence trials. Emphasis is on practical use of methods rather than formal statistical theory.

Texts & Reading:

Drug and Device Development

Course Director: J. Matthew Luther, MD, MSCI
Summer [3 hours credit] Luther

This seminar styled course is designed to provide an overview of the drug and device development process and will include issues of drug discovery, pre-clinical drug development, Phase I through IV human testing, device development and the role of the FDA in regulatory affairs. Learning objectives will include:

1. An overview of the process of drug development from initial compound discovery, through clinical trials, to post-marketing issues;

2. An overview of device development, and to be able to contrast this to the process of drug development; and

3. An introduction and some insight into the function of the Food & Drug Administration (FDA).
Epidemiology I

Course Director: Karel G.M. Moons, PhD
Professor of Epidemiology, University of Utrecht
Fall [4 hours credit] Moons

The course will provide an introduction to the principles of the design and analyses of evidence based clinical studies. The course will cover the concept of causation versus prediction, the design of (clinical) epidemiological research, measures of disease frequency and association, validity issues including confounding, and the generalizability of research to practice. Subsequently the course addresses in more detail the design and analysis of diagnostic, prognostic, therapeutic, and etiologic (side effects) research.

Texts & Reading:
Grant Writing

Course Director: Sunil Kripilani, MD, MSc, SFHM
Summer [1 hour credit]

Principles of scientific written and oral communication, with a focus on grant writing will be discussed. The principles of scientific grant writing will include how to write the background and significance, previous work, and methods sections. Students will review grants submitted to public health service study sections, participate in a mock study section, and prepare a sample grant application. Enrollment is limited.
Trainees will participate in this course throughout the first and second years of the MSCI program. The Master’s Research course, along with the Case Studies series, is designed to guide trainees to the successful completion of the Master’s Final project.

All trainees are required to spend a minimum of 80% time in research activities, which include didactic coursework and activities within the mentor’s lab.
Medical Writing for Clinical Investigators

Course Director: Daniel Byrne, MS
Spring [2 hours credit] Byrne

This course is designed to teach clinical investigators medical writing skills required to publish scientific articles in a peer-reviewed medical journal. Since trainees in the MSCI program are expected to complete their Master’s thesis based on their research project in the Spring of year 2, this course is scheduled prior to this deadline to assist students in writing their thesis/paper. Teaching will consist of demonstrations and discussions of how to improve the writing quality using each student’s thesis-in-progress as an example. Students will be expected to write and revise their Master’s thesis as course-work, no additional written assignments will be required.
The goal of this course is to provide an overview of molecular medicine and update the students’ knowledge base in this rapidly evolving field. Lectures cover broad topics and are intended to help students understand and explore primary literature and to inform students on available molecular resources that can complement their own research interests. Each module of the course will consist of a two hour didactic lecture delivered by basic science faculty addressing a fundamental process of molecular biology. Each lecture will be followed by a one hour group discussion where the class is divided into 2 groups, each with a facilitator. The group discussion will focus on the topic of the lecture, with an opportunity for students to discuss their own reading they have done in preparation for the lecture. Specific research methods and experimental systems not covered in the lectures will also be discussed.

Texts & Readings:

- Recommended: Alberts et al, eds: Molecular Biology of the Cell
Research Ethics and Scientific Integrity

Course Director: Elizabeth Heitman, PhD
Spring [1 hour credit] Heitman

This course is a systematic examination of the ethical concepts and standards of responsible conduct of research in biomedical science and clinical investigation. Its aim is to provide post-doctoral and graduate trainees in clinical research a framework in which to recognize, examine, resolve, and prevent ethical questions and conflicts in their professional work.

Objectives:
Upon successfully completing this class, students will be able to:
1. Trace the historical development and critique concepts of scientific integrity and research ethics – including legal and socio-religious influences – in biomedical science and clinical investigation;

2. Recognize, identify, and analyze questions central to the ethical problems in biomedical science and clinical research using relevant professional and regulatory standards.

3. Formulate recommendations for preventing and/or resolving ethical conflict in biomedical science and clinical research and promoting responsible conduct of research; and

4. Identify the appropriate institutional resources for addressing questions related to ethics and integrity in biomedical science and clinical research in academic and nonacademic settings.
Selected Elective Courses

**BMIF300 Foundations of Biomedical Informatics**
This introductory course examines the unique characteristics of clinical and life science data and the methods for representation and transformation of health data, information, and knowledge to improve health care. Principles of information security and confidentiality are taught, along with functional components of information systems in clinical settings and the use of databases for outcome management. Through skill modules, the course provides an introduction to methods underlying many biomedical informatics applications, including information retrieval, medical decision making, evaluation of evidence and knowledge representation. The historical evaluation of the field of biomedical informatics is taught concurrently, using examples of landmark systems developed by pioneers in the field.
FALL [3] S Weinberg

**CANB340 Introduction to Cancer Biology**
A multi-disciplinary course designed to expose students to all areas of basic and applied cancer research. Emphasizes the molecular mechanisms underlying carcinogenesis and tumor progression and their relationship to clinical aspects of the disease.
Fall [4 hours credit] Yull

**HGEN 333 Analytic Techniques for Genetic Epidemiology**
This course will take an example-based approach to provide students with the skills necessary to conduct statistical association analysis of genetic data from human populations for genetic epidemiology studies. Topics will include quality control, statistical methods for association testing, common study design issues, future directions of genetic epidemiology and advanced topics.
Selected Elective Courses

**HGEN 340 Human Genetics I**
Designed to cover background and latest advances in human genetics. Topics will include an overview of mutational mechanisms, cytogenetics (detection and description of chromosomal abnormalities), biochemical genetics (gene defects in biochemical pathways, inborn errors of metabolism), molecular genetics (gene structure, function, and expression). Topics are discussed with reference to specific human genetic diseases.
FALL [3] Russell and Mortlock

**MSCI 5028 Data Management (alternate years – even)**
The objective of this course is to teach students the fundamentals of research data planning, collection, storage, dissemination and manipulation. Several software tools will be employed, but primary ideas should transcend individual applications (especially versions) and ultimately serve students by providing tools for use in data management for clinical investigation.

Specific goals of instruction in the course include:
1) Microsoft Excel – General to Advanced, 2) Data visualization and graphical methods, 3) Software spectrum for clinical research, 4) Productivity tips/tricks to save time (for research), 5) Practical techniques for managing research data, 6) Database theory and implementation, 7) Data collection strategies, 8) Using public health databases (freely available), 9) SQL methods for DB interface – repackaging and filtering data, 10) Easy programming methods to solve repetitive tasks, 11) Data security and best practices.
Spring [2 hours credit] Harris
Selected Elective Courses

PUBH Epidemiology II: Non-Randomized Study Design
The design of observational studies, including factors that are important in design selection. The design of cohort studies, including rationale for use of the cohort study, prospective and retrospective cohort studies, assembly and follow-up of the cohort, exposure measurement, outcome ascertainment, confounders, effect modification, calculation of measures of occurrence and effect, summary of multivariate statistical analyses for cohort studies. The case-control study, including rationale for use, conditions necessary for validity of the case-control study, selection of controls, sources of bias in case-control studies, and multivariate analysis. The ecological study, including when to use and when to avoid. Designs to usually avoid: cross-sectional, case-series and exposed-subject designs. The course includes didactic lectures and critical reading of important epidemiologic studies from the current medical literature. The latter encompasses discussion of the articles in small groups and structured presentation to the class. The course also includes a project, which is the development and presentation of a study design protocol to the class. This protocol is for the project that will serve as the student’s master’s thesis. Prerequisites: Epidemiology 1, Biostatistics 2, Clinical Trials, or approval of instructor. Enrollment is limited to 24 students, with priority given to MPH and MSCI students.
Spring [4 hours credit] Ray

MSCI 5016 Research Skills
This course offers basic instruction and practical advice on a variety of issues and skills related to the conduct of clinical research, often with computer demonstrations.
Fall and Spring [1 hour credit] Orozco
Admission to Individual Classes
Individual classes in the MSCI Program may be taken for credit by students not enrolled in the MSCI Program at the individual course tuition rate established by the Vanderbilt Board of Trust. Students admitted to individual courses must be eligible to apply for admission to the MSCI program. Exceptions may be made by the Program Director in consultation with the Course Director for classes in which certain admission requirements (such as clinical experience) are not necessary for participation in the course. Admission to individual classes is also contingent upon availability of space in the course. (See also: Auditing Classes)

Admission Requirements
Eligible candidates for the MSCI Program include:

- Board-eligible physicians enrolled in a fellowship program at Vanderbilt or Meharry Medical College,
- Residents with protected time for research,
- Vanderbilt faculty members with the consent of their Department Chair,
- Medical students in the Vanderbilt Medical Scholars Program,
- Post-Doctoral PhDs anticipating a career in patient-oriented research, and
- PhD candidates in the Nursing School anticipating a career in patient-oriented research.
- Scholars external to Vanderbilt/Meharry will be considered based on the availability of a suitable mentor within Vanderbilt and secured funding.

Applications will be judged on the quality of the science proposed, on the commitment of the mentor to the career development of the candidate, and on the overall impact of the training program on the applicant’s career development.
**Requirements for Graduation**

To meet graduation requirements for the MSCI, student must have completed 35 hours of coursework with grades approved by the MSCI program and submission of a final project in the form of one of following:

- a submission ready extramural grant, or
- a submitted or submission-ready original article to a peer-reviewed journal

In the case that these two items cannot be completed, a thesis can be submitted. The thesis should include a brief introduction explaining why a grant or manuscript could not be prepared and submitted on a timely basis. Thesis submission is subject to preliminary approval by the MSCI directors.

It is recommended that a thesis include:

- No oral presentation is required.
- The thesis should include
  1. a brief statement of the student’s role in the work to be described in the research report
  2. 10-15 page research report outlining the hypothesis tested, background and significance of the work, the experimental approach and methods, data analysis/sample size calculations, anticipated results and pitfalls, results to date, interpretation of results, discussion of results, and future plans.

The subsequent step in the graduation process is a review and approval of each student’s manuscript, grant or thesis by our Promotions Committee.

It is anticipated all the students will complete the graduation requirements by the end of the fifth semester of enrollment. In the case of any potential delays, the student is allowed to extend the graduation date six months twice (total of one year). In unusual circumstances (including, but not limited to health problems, change of jobs, move to another institution) an additional extension up to one year will be granted. During a period of extension, the student will be enrolled in the Research Extension course, a status which incurs no tuition costs.
**Student Status: Full-time or Part-Time**

Full Time (Fall & Spring Terms)
*Registered for 8 or more hours*

Half-Time (Fall & Spring Terms)
*Registered for at least 4 hours but less than 8 hours*

Less than Half-Time (Fall & Spring Terms)
*Registered for a course but less than 4 hours*

Full Time (Summer Term)
*Registered for 6 or more hours*

Half Time (Summer Term)
*Registered for at least 3 hours but less than 6 hours*

Less than Half-time (Summer Term)
*Registered for a course but less than 3 hours*

Two courses, Master’s Research and Research Extension, automatically trigger full-time status.
**Grading Policy**
Students in the Master of Science in Clinical Investigation Program will be evaluated in each course. Letter grades will be given by the course director, based on attendance, class work, homework, test results, and final exams.

Letter grades will be awarded as follows:

- A+ = 4.0
- A = 4.0
- A- = 3.7
- B+ = 3.3
- B = 3.0
- B-= 2.7
- C+ = 2.3
- C = 2.0
- C- = 1.7
- D+ = 1.3
- D = 1.0
- D-= 0.7
- F = 0.0

Only courses with a grade of B- or better will count towards the MSCI Program requirements. Courses for which a grade of C+ or lower is awarded will need to be retaken.

Master’s Research, Research Extension, and Case Studies courses are graded on a pass/fail scale and are not considered in calculation of GPA.

**Auditing**
Auditing of MSCI classes may only be allowed if the class has less than ten registered participants. Any class with over ten registered participants will not allow audits. This policy is applicable to courses administered by the MSCI program.
Acceptance of Transfer Credits
The MSCI Program allows matriculated students to transfer equivalent graduate level courses taken up to two years’ prior to admission into the Vanderbilt MSCI program. The procedure for an applicant to have credit considered for transfer is to send a letter requesting approval for transfer of the course(s), along with the student’s transcript(s) and the course syllabi. Only courses taken at accredited institutions will be considered; a maximum of 9 credit hours are allowed for transfer into the MSCI program. Determination of equivalency will be made by the Program Director in consultation with the Course Director.

If courses taken prior to admission into the Vanderbilt MSCI program are determined to meet graduation requirements, tuition will be reduced at the per-credit hour rate of the requirement that is met by the transfer.

Grievance Procedures
Students who believe their academic performance has not been judged reasonably or fairly, or who believe their intellectual contributions have not been fairly acknowledged, should consult the Program Director. The MSCI program follows procedures described in the School of Medicine handbook, which include encouraging the student to seek redress of a problem as soon after receiving the grade and in no case later than six months after the event.

A Director of the MSCI Program will serve as liaison and counselor for issues that arise between mentor and trainee. For a situation that cannot be resolved with the assistance of an MSCI Director or a grievance that may arise between a trainee and the MSCI program, a grievance committee will be assembled. The grievance committee will consist of the Senior Associate Dean for Faculty and Administrative Affairs or designate, two MSCI mentors unaffiliated with the involved parties, and the MSCI Student Representative.

The grievance committee will assemble the details of the situation and make a written recommendation that is presented to the Directors of the MSCI program and to the grievant, who may provide written comment on the recommendations.

The Directors of the MSCI program will review all of the relevant materials, reach a conclusion on the resolution of the grievance, and send a written copy of the final recommendation to the grievant. The grievant may appeal this decision to the Dean of the School of Medicine.
Vanderbilt University
Master of Science in Clinical Investigation

PROGRAM OFFICE
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