

INVESTIGATIVE MEDICINE

2 Church Street South, Suite 113
<http://medicine.yale.edu/investigativemedicine>
 Ph.D.

Director of Graduate Studies

Joseph Craft (joseph.craft@yale.edu)

Deputy Director

Eugene Shapiro (eugene.shapiro@yale.edu)

Professors Karen Anderson (*Pharmacology*), Joseph Craft (*Internal Medicine; Immunobiology*), James Dzuria (*Emergency Medicine*), David Fiellin (*Internal Medicine; Epidemiology*), Thomas Gill (*Internal Medicine; Epidemiology*), Fred Gorelick (*Internal Medicine; Cell Biology*), Jeffrey Gruen (*Pediatrics; Genetics*), Harlan Krumholz (*Internal Medicine; Epidemiology*), Eugene Shapiro (*Pediatrics; Epidemiology*), George Tellides (*Surgery*), Mary Tinetti (*Internal Medicine*)

FIELDS OF STUDY

The Investigative Medicine program offers a training pathway for highly selected physicians in clinical departments who are interested in careers in clinical research. The program is designed to develop a broad knowledge base, analytical skills, creative thinking, and the hands-on experience demanded of clinical researchers devoted to disease-oriented and patient-oriented investigation. The program provides the student with individualized experience encompassing formal course work and practical experience, under the supervision and mentorship of a graduate school faculty member.

Students will enter the program with a broad range of experience and interests. Students can undertake thesis work in a variety of disciplines. These include but are not limited to:

1. Evaluating risk factors and interventions for disease using modern concepts in quantitative methods and clinical study design,
2. Investigating the biochemical, physiologic, and genetic basis of disease including in the setting of a clinical research center, and
3. Exploring the molecular basis of disease in the laboratory.

For more information on the admissions process and course details please visit the Investigative Medicine Program website: <https://medicine.yale.edu/investigativemedicine>.

SPECIAL REQUIREMENTS FOR THE PH.D. DEGREE

The minimum overall course requirements for the doctorate program are completion of six required courses plus two electives, either in laboratory-based patient-oriented research or clinical-based patient-oriented research. The majority of required courses are to be completed by the end of the first year of study. Prior to registering for a second year of study, students must have successfully completed IMED 630, Ethical Issues in Biomedical Research. Electives are often taken in the second year, in addition to IMED 665, with the expectation that courses be completed by the end of the second

year of study. To be eligible to take the comprehensive qualifying examination, students must achieve the grade of Honors in two courses, have a minimum grade average of High Pass, and have completed a minimum of six courses. When these latter course requirements are met, at least by end of the fall term of the second year, students undertake the comprehensive qualifying examination. In order to be admitted to candidacy, students must pass both a written and oral comprehensive qualifying examination and submit a thesis prospectus that has been approved by their qualifying committee. The remaining degree requirements include completion of the dissertation project, writing of the dissertation, and its oral defense. It is expected that students will complete the program in three to five years. There is no foreign language requirement. The minimum required curriculum for each program of study is as follows:

Course Requirements

LABORATORY-BASED PATIENT-ORIENTED RESEARCH

IMED 625	Principles of Clinical Research	1
IMED 630	Ethical Issues in Biomedical Research	1
IMED 635	Directed Reading in Investigative Medicine	1
IMED 645	Introduction to Biostatistics in Clinical Investigation	1
IMED 665	Writing Your K- or R-Type Grant Proposal	1
IMED 680	Topics in Human Investigation	1

Two electives: one bioinformatics course and one discipline-based course. Director approval required.

CLINICAL-BASED PATIENT-ORIENTED RESEARCH

IMED 630	Ethical Issues in Biomedical Research	1
IMED 635	Directed Reading in Investigative Medicine	1
IMED 661	Methods in Clinical Research, Part II	1
IMED 662	Methods in Clinical Research, Part III	1
IMED 665	Writing Your K- or R-Type Grant Proposal	1
IMED 680	Topics in Human Investigation	1

Two electives. Director approval required.

COURSES

IMED 625a, Principles of Clinical Research Eugene Shapiro

The purpose of this intensive two-week course is to provide an overview of the objectives, research strategies, and methods of conducting patient-oriented clinical research. Topics include competing objectives of clinical research, principles of observational studies, principles of clinical trials, principles of meta-analysis, interpretation of diagnostic tests, prognostic studies, causal inference, qualitative research methods, and decision analysis. Sessions generally combine a lecture on the topic with discussion of articles that are distributed in advance of the sessions.

IMED 630a, Ethical Issues in Biomedical Research Lauren Ferrante

This term-long course addresses topics that are central to the conduct of biomedical research, including the ethics of clinical investigation, conflicts of interest, misconduct in research, data acquisition, and protection of human subjects. Practical sessions cover

topics such as collaborations with industry, publication and peer review, responsible authorship, and mentoring relationships. Satisfactory completion of this course fulfills the NIH requirement for training in the responsible conduct of research.

IMED 635a or b, Directed Reading in Investigative Medicine Joseph Craft

An independent study course for first-year students in the Investigative Medicine program. Topics are chosen by the student, and reading lists are provided by faculty for weekly meetings to discuss articles. Four sessions are required; dates/times by arrangement. Consent of instructor required.

IMED 645a, Introduction to Biostatistics in Clinical Investigation Veronika Shabanova

The course provides an introduction to statistical concepts and techniques commonly encountered in medical research. Previous course work in statistics or experience with statistical packages is not a requirement. Topics to be discussed include study design, probability, comparing sample means and proportions, survival analysis, and sample size/power calculations. The computer lab incorporates lecture content into practical application by introducing the statistical software package SPSS to describe and analyze data.

IMED 661a, Methods in Clinical Research, Part II Eugene Shapiro

This yearlong course (with IMED 660 and 662), presented by the National Clinical Scholars Program, presents in depth the methodologies used in patient-oriented research, including methods in biostatistics, clinical epidemiology, health services research, community-based participatory research, and health policy. Permission of instructor required.

IMED 665a or b, Writing Your K- or R-Type Grant Proposal Eugene Shapiro

In this term-long course, students gain intensive, practical experience in evaluating and preparing grant proposals, including introduction to NIH study section format. The course gives new clinical investigators the essential tools to design and initiate their own proposals for obtaining grants to do research and to develop their own careers. The course is intended for students who plan to submit grant proposals (for either a K-type career development award or an R-type investigator-initiated award). Attendance and active participation are required. There may be spaces to audit the course.

IMED 680b / B&BS 680b, Topics in Human Investigation Joseph Craft and Karen Anderson

The course teaches students about the process through which novel therapeutics are designed, clinically tested, and approved for human use. It is divided into two main components, with the first devoted to moving a chemical agent from the bench to the clinic, and the second to outlining the objectives and methods of conducting clinical trials according to the FDA approval process. The first component describes aspects of structure-based drug design and offers insight into how the drug discovery process is conducted in the pharmaceutical industry. The format includes background lectures with discussions, labs, and computer tutorials. The background lectures include a historical perspective on drug discovery, the current paradigm, and important considerations for future success. The second component of the course provides students with knowledge of the basic tools of clinical investigation and how new drugs are tested in humans. A series of lectures and discussions provides an overview of the objectives, research strategies, and methods of conducting patient-oriented

research, with a focus on design of trials to test therapeutics. Each student is required to participate (as an observer) in an HIC review, in addition to active participation in class. Consent of instructor required.