INVESTIGATIVE MEDICINE

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Ph.D.

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FIELDS OF STUDY

The Investigative Medicine program offers a training pathway for highly select 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 senior 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 in the setting of a Clinical Research Center.
3. Exploring the molecular basis of a disease from the laboratory standpoint.

SPECIAL REQUIREMENTS FOR THE PH.D. DEGREE

The minimum overall course requirements for the doctorate program are completion of nine (9) courses. Intensive course work will extend for twelve months, starting in July. The majority of the course requirements are to be completed by the end of the first year of study. Prior to registering for a second year of study, students must successfully complete IMED 630, Ethical Issues in Biomedical Research. In addition to IMED 655, electives are often taken in the second year, with the expectation that they be completed by the end of the second year. To be eligible to take the comprehensive qualifying examination, students must achieve the grade of Honors in two courses (one course if a full-year course), have a minimum grade average of High Pass, and have completed a minimum of six courses. When requirements are met (typically by
December 31 of the second year), students submit their thesis proposal and undertake the comprehensive qualifying examination. In order to be admitted to candidacy, students must pass both the written and oral comprehensive qualifying examinations 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 most 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 for Laboratory-Based Patient-Oriented Research

IMED 625, Principles of Clinical Research
IMED 630, Ethical Issues in Biomedical Research
IMED 635, Directed Reading in Investigative Medicine
IMED 645, Introduction to Biostatistics in Clinical Investigation
IMED 655 or IMED 665 or IMED 670: Writing Your K- or R-Type Grant Proposal
IMED 680, Topics in Human Investigation
CBIO 601, Science at the Frontiers of Medicine
CB&B 740, Clinical and Translational Informatics
Elective (1)

Course Requirements for Clinically Based Patient-Oriented Research

IMED 630, Ethical Issues in Biomedical Research
IMED 635, Directed Reading in Investigative Medicine
IMED 655 or IMED 665 or IMED 670: Writing Your K- or R-Type Grant Proposal
IMED 660, Methods in Clinical Research, Part I
IMED 661, Methods in Clinical Research, Part II
IMED 662, Methods in Clinical Research, Part III
IMED 680, Topics in Human Investigation
Electives (2)

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 research 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 Responsible Conduct of Research. Format consists of lecture presentation followed by discussion. Permission of instructor required.

**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 and Eugene Shapiro
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 655b, Writing Your K- or R-Type Grant Proposal (I)** 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 660a, Methods in Clinical Research, Part I** Eugene Shapiro
This yearlong course (with IMED 661 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 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 662b, Methods in Clinical Research, Part III  Eugene Shapiro
This yearlong course (with IMED 660 and 661), 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, 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 670b, Writing Your K- or R-Type Grant Proposal (II)  Eugene Shapiro
In this term-long course, students gain intensive, practical experience in evaluating and preparing grant proposals, including discussion of NIH study section format. The course is particularly designed to help investigators in the “K to R” transition period. 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, as well as VA and foundation grant proposals). Attendance and active participation are required.

IMED 680b / B&BS 680b, Topics in Human Investigation  Joseph Cra 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.