

The Human Investigations Program curriculum consists of a set of required core courses and elective courses offered over a two-year period. The courses are offered in a fixed sequence during the two years with opportunities for electives in the second year. A seminar series, the HIP Buffet, offers topical information about research and occasional presentations from select faculty members. Students will be offered graduate level academic credit for each course. There are three tracks for which a candidate may apply:

- **Certificate Track**

The certificate track includes the required courses in the first and second years, a choice of elective courses, plus a mentored capstone experience resulting in an academic product such as a research proposal or publishable manuscript. Individuals completing this track will receive at least 25 graduate level credit hours and a Certificate in Human Investigations (24 graduate level credits for students admitted prior to Fall 2009).

- **Master of Clinical Research Track**

A master's degree track focuses on formal training for health care professionals who desire to make clinical research either their predominant focus or a substantial part of their long-term career goals. This track requires approximately twice as many credit hours as is offered in the certificate track. In addition to completing all courses offered through the HIP curriculum and a mentored capstone project, trainees choose electives offered by the HIP program and from other graduate programs at OHSU including Public Health and Preventive Medicine, Biomedical Informatics and all graduate courses in basic science in the School of Medicine, and any graduate courses in the School of Nursing. This track is only available to trainees already enrolled in the certificate track or who have recently completed the certificate. Individuals completing at least 45 graduate level credit hours and all program requirements will receive a Master of Clinical Research degree.

- **Non-degree Track**

The non-degree track allows students to select specific courses in clinical research. This track does not include a mentored experience or degree. This may fulfill a requirement for research training in some department fellowships. Courses can be taken for graduate level credit or for audit. Pre-registration is required and enrollment is based on space available.

Seminar Series:

The HIP Buffet, an every other week noontime seminar alternating Tuesdays and Wednesdays, offers students short presentations on practical topics related to clinical and translational research, protocol development, scientific writing, research budgets and career development. This two-year topic series is designed with the needs of the student in mind.

Course Descriptions Academic Year 2009-2010.

Most class sessions are held for two hours each, one day a week unless otherwise noted. See HIP course schedule for dates – courses may not begin or end with Academic terms.

HIP 510 Introduction to Clinical Research, 1-day orientation session (1 credit) - Required for Certificate and MCR

Course Director: Cynthia Morris, PhD, MPH

Format: Informational presentations, interactive exercises, discussion

The specific goal of Introduction to Clinical Research is to educate trainees in the essential nature of research design and in the basic process of building a patient-oriented research study. Discussions include the essential elements of a career in clinical research and opportunities for obtaining early career funding. This module uses faculty who are experienced investigators, capable teachers, and administrators of major OHSU and VAMC research services. The lecturers discuss the principles of their topic while using examples from their own areas of research, and provide an introduction to campus research leaders. Although didactic methods are employed, there is also emphasis on discussion, and, as often as possible, trainees engage in practical exercises in the process of developing and maintaining a research career and establishing a mentoring relationship. This course provides the foundation for the full 2-year Human Investigations Program.

Offered: Fall term, one day only.

HIP 511F/W Clinical Research Design I&II, 19 weeks total (4 credits) – Required for Certificate and MCR

Course Director: Thomas Becker, MD, PhD

Format: Interactive classroom lectures and small group sessions

This course is the cornerstone of HIP. The goal is to educate trainees in the nature of clinical research and in the basic process of building a patient-oriented research study. HIP 511 provides interactive classroom lectures with trainees conducted much as an epidemiologic methods course, with emphasis on causal inference, measures of association, bias, confounding, and strengths and weaknesses of various study designs. Examples of studies are presented from current journals, and the trainees are asked to react to different features of articles that are presented in an abbreviated format. Screening for disease will be discussed, focusing on evaluation, study design, and implementation. In Spring term, the course continues after a term of biostatistics (HIP 512 Biostatistics) to provide more in depth study of research design with integration of biostatistical methods.

Offered: Fall and continues in Spring term

HIP 511A Protocol Development, 6 sessions (3 credits) – Required for Certificate and MCR

Offered in conjunction with HIP 511 Clinical Research Design and HIP 512 Biostatistics, this course offers a small group session experience in which trainees develop a hypothesis and clinical research study. Intertwined with lectures in HIP 511 and HI 512, trainees will meet a total of 6 times in small groups led by experienced clinical research faculty members to discuss research ideas and methods for testing specific hypotheses. At each session, trainees complete a written assignment that is similar to required sections of any grant. In the end, the assignments are put together as a complete grant proposal, with the exception of budget. The trainees present their written assignments in small groups and are critiqued by peers and faculty.

Note: HIP 511A must be taken in conjunction with HIP 511 or with permission, the following year. No auditors allowed in HIP 511A.

Offered: Must be enrolled Fall, Winter and Spring terms

HIP 512 Biostatistics, 9 weeks (2 credits) – Required for Certificate and MCR

Course Directors: Mike Lasarev, MS

Format: Didactic learning

In Biostatistics trainees learn basic concepts in probability, estimation, and hypothesis testing as well as statistical methods frequently used in clinical research. The objectives of the course are to provide familiarity with basic statistical concepts and issues in clinical research, enable effective communication with biostatisticians, and form collaborative relationships, while teaching simple data analysis. The module covers the following topics: descriptive statistics, probability, confidence intervals, hypothesis testing, ANOVA, linear and logistic regression, categorical data analysis, and non-parametric tests.

Offered: Winter term

HIP 512A Biostatistics Lab, 9 weeks (1 credit) – Elective

Course Directors: Mike Lasarev, MS

Format: Experiential learning, Online modules

In this optional module, paired with HIP 512 Biostatistics, students will learn to use STATA to explore the data and perform simple data analysis. Students will learn to work with files, some descriptive statistics, cross tabulations, and graphing. **Note:** Must be taken concurrently with HIP 512

Offered: Winter term

HIP 514 Molecular Biology for Clinical Research, 8 weeks (2 credits) – Required for Certificate and MCR

Course Director: Cheryl Maslen, PhD

Format: Large groups lectures

The power of contemporary methods in molecular and cell biology to reveal complex mechanisms of pathogenesis has increased geometrically over the past 25 years. With completion of the human genome project, and with new technologies for genomic screening and bioinformatics, clinician scientists have unique opportunities to rapidly define pathways of disease pathogenesis. They must be well trained in fundamental concepts of basic research technologies in fields of molecular and cell biology, biochemistry and molecular pharmacology. Similarly, basic researchers require training in clinical research methods. The lectures review important molecular biology methods frequently encountered with an emphasis on how these techniques can be useful in clinical studies. The objectives are to provide a fully integrated experience for both basic and clinician scientists in fundamentals of translational clinical research. Three conceptually linked strategies are used: 1) lectures covering molecular techniques, 2) in-class participation in topical discussions, and 3) project

development in trainee's area of interest utilizing the methodologies covered in the course. This course is taught by clinician scientists with expertise in applying molecular biology to translational research, which allows for clinical correlation and application of the subject matter. Specific topics include genetic and genomic technologies, gene discovery, gene expression analysis, linkage mapping, genome-wide association studies, transgenic models, stem cell biology, bioinformatics, and proteomics.

Offered: Fall term

HIP 516 Protection of Human Subjects, 4 weeks (1 credit) – Required for Certificate and MCR

Course Director: Gary Chiodo, DMD, FACD

Format: Large-group lecture, case-based, interactive discussion, attendance of an IRB meeting.

This module enables clinical researchers to recognize and appropriately address legal, regulatory, and ethical issues in research, with special attention to vulnerable subjects and regulatory issues unique to Oregon. This is accomplished by 1) teaching basic concepts in law, federal regulation, study design, and ethics related to clinical research; 2) reviewing common problems encountered in human subjects protocols and informed consent documents to demonstrate how to identify and remedy deficiencies; 3) reviewing the roles and responsibilities of institutional review boards, investigators, sponsors, study coordinators, and all others involved in the conduct of human research; 4) reviewing the obligations of clinical researchers in relation to initial and continuing reviews, reporting of unanticipated problems, reporting changes in approved research, and consenting and monitoring human subjects as required by federal regulations; and 5) focusing on the need to develop policies and procedures to best safeguard and protect all vulnerable subjects. The module includes discussion of the historical roots for current regulations, Oregon law, federal regulations, OHSU policies, and practical advice for navigating the compliance milieu related to human subjects research.

Offered: Fall term.

HIP 517 Scientific Writing and Data Presentation, 6 weeks (1.5 credits) – Required for Certificate and MCR

Course Director: Leon Assael, MD

Format: Seminar series with case-based learning

Success in clinical research rests on the researcher's ability to communicate the findings of research clearly and effectively. The purpose of this course is to provide insight into the peer-reviewed journal process in clinical medicine and surgery. The trainee also gains an understanding of the elements of clinical science writing that are expected in peer-reviewed publications. The topics covered include elements of the clinical science paper; writing the paper from concept to manuscript; defining the peer-reviewed literature; finding appropriate and best journals for submission; elements of peer review including how to review and how to respond to reviewers' comments. This module also explores the art of oral presentation of scientific data.

Offered: Winter term.

HIP 507A Evidence-based Medicine Seminar, 8 weeks (2 credits) – Required for Certificate and MCR

Course Directors: Michelle Berlin, MD, PhD and Paul Gorman, MD

Format: Small group seminar series

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of patients. It is the integration of the results from clinical research and clinical judgment. The evidence-based medicine seminar introduces trainees to the broad array of clinical research designs used in published studies. Trainees learn basic approaches to evaluating the validity of various study designs used in published research and identify the advantages and disadvantages of various methods of presenting the results of a study (e.g., relative risk reduction versus absolute risk reduction). As they learn about clinical research design in other courses, the trainees have the opportunity to immediately apply that knowledge by critically reading recently published studies in the EBM seminar. This module is conducted through small group discussion and caps the learning process from the previous 18 months of HIP courses through critically reading and appraising the literature.

Prerequisites: HIP 511 and 512

Offered: Winter term, credits divided between winter and spring terms

HIP 518 Introduction to Outcomes Research, 4 weeks (1 credit) – Required for Certificate and MCR

Course Director: Jessina McGregor, PhD

Format: Large group lectures, interactive exercises, interactive discussion

A large part of the evidence about safety and effectiveness of different treatments is based on retrospective studies. This course will provide a survey of outcomes research methods using a sample dataset. Emphasis is placed on integrating statistical and clinical thinking to construct models that are both statistically and clinically sound and that give accurate predictions when generalized to other populations. This module builds on previous courses in biostatistics, evidence-based medicine, and research design. Topics on confounding and bias, and statistical adjustment are presented from different viewpoints that often crystallize these concepts within the health services model. Through an active lecture and problem-solving discussion, trainees are taught to recognize the causes of variation in practice and in outcome; understand the major types of study designs used in outcomes research; and become familiar with types of data used in outcomes studies, and the strengths and weaknesses of different data sources.

Prerequisites: HIP 511 and 512

Offered: Spring term.

HIP 520 Medical Informatics, 6 weeks (1.5 credits) - Elective

Course Director: William Hersh, MD

Format: On-line lectures and threaded on-line discussions

Medical informatics is described as “the rapidly developing scientific field that deals with the storage, retrieval, and optimal use of biomedical information, data, and knowledge for problem solving and decision making.” An understanding of medical informatics is crucial to clinical researchers. The widespread adoption of electronic medical records and the emerging standards on which they are based will influence how researchers acquire and use patient data; the revolution in bioinformatics may fundamentally alter how we view and research disease; and growing concerns over confidentiality of health information, most notably HIPAA regulations, determine how patient information is stored and used. Course topics include fundamentals of medical computing, electronic medical records, data interchange and terminology standards, information retrieval from databases, security and confidentiality, and bioinformatics. The course consists of on-line lectures with assignments that include hands-on use of electronic medical records, decision support applications, and information retrieval systems; reading assignments; and threaded on-line discussions.

Offered: Summer term.

HIP 522 Fundamental of RCTs, 6 weeks (1.5 credits) - Elective

Course Directors: Cynthia Morris, PhD, MPH

Format: Large group lectures, interactive exercises, interactive discussion

This course covers the principles of clinical trial design, implementation, and management, including single- and multi-center trials. Each trainee is expected to develop a working protocol for a clinical trial as a result of this class, and to read and critically appraise published trials. Conventional trials of drug treatment will be discussed, with special emphasis on conducting trials of alternative medicines, surgical or device therapy, and nutritional and other interventions requiring counseling. Each class period includes discussion, in a journal club format, of a recently published clinical trial that illustrates the lecture topic.

Offered: Spring term, every other year.

HIP 523 Computerized Data Management, 6 weeks (1.5 credits) – Elective

Course Director: Robert Schuff, MS

Format: Didactic learning paired with experience in a data lab environment

This course introduces trainees to the fundamental principles of clinical research data management and clinical appropriate data management practices, and provides them with an understanding of database design. It is structured as a mixture of didactic and hands-on lab. At the end of the course, trainees should have an understanding of the clinical data management lifecycle; appreciate the importance of beginning the data management process early in the project; and possess basic understanding and proficiencies in database design with Microsoft Access. Topics discussed include: creation of case report forms, types of database systems including relational databases, data validation, standards, missing data, data security and integrity, data entry, and queries and reporting. Trainees are also introduced to resources for data management available at OHSU.

Offered: Spring term.

HIP524 Effective Clinical Teaching Methods, 6 weeks (1.5 credits) – Elective

Course Director: Judy Bowen, MD

Format: Small group seminar series with case-based learning

This elective is designed for clinical teachers who wish to enhance their abilities as educators through a deeper understanding of teaching and learning, and the development of specific instructional skills. In this course, participants identify characteristics of effective teaching that enhance learning, learn a framework for understanding developmental learning stages and expectations for learners at different levels, and identify challenges in teaching multiple levels of learners. Instructional skills are taught for different settings, such as effective large group presentations, effective case-method teaching, and the “one-minute-preceptor” teaching technique for one-on-one teaching. Students also learn a framework for “diagnosing” learner reasoning and identify effective questioning strategies that enhance the teacher’s ability to “diagnose” learners.

Offered: Spring term.

HIP526 Capstone – Mentored Experience (6 credits) – Required for Certificate and MCR

The mentored experience is the centerpiece of HIP and is designed to create independent clinical investigators. The mentored experience results in an academic product, either a grant submission or peer-reviewed publication. Developing a research proposal with a mentor allows the trainee the optimal opportunity to experience all the steps in this process. These include reviewing the background literature, developing a hypothesis and specific aims, designing an appropriate and fundable study to answer the hypothesis, formulating the statistical analysis, and refining the written work to maximize fundability. This exercise replicates the critical experience necessary to creating an independent, funded research program.

Offered: Each term.

HIP 527 Systematic Reviews, 8 weeks (2 credits) – Elective

Course Directors: Susan Norris, MD, MSc, MPH and Marian McDonagh, PhD,

Format: Didactic learning, interactive exercises, interactive discussion

This course will introduce students to the methodology of systematic reviews by working through the steps of a review using examples and discussion to explore various methodological approaches and identifying quality standards. Students will be asked to read and evaluate systematic reviews, discuss the process of reviews, and to consider various methodological approaches, including the pros and cons or suitable context for each. At the end of the course, students will feel comfortable reading, evaluating and applying systematic reviews from the perspective of a user.

Prerequisites: HIP 511, 511A and 512.

Offered: Fall term.

HIP 528 Applied Biostatistics I, 11 weeks (3 credits) – Elective

Course Director: Dawn Peters, PhD

Format: Didactic learning paired with experience in use of statistical software.

This course, expanding on topics explored in the HIP 512 biostatistics course, will focus on multivariable methods widely used in clinical research: linear regression, logistic regression, survival analysis, and repeated measures analysis.

Prerequisites: HIP 511, 511A and 512.

Note: Class sessions held for three hours each, one day a week

Offered: Winter term.

HIP 529 Applied Biostatistics II, 11 weeks (3 credits) – Elective

Course Director: Jodi Lapidus, PhD

Format: Didactic learning paired interactive discussion.

This course explores some advanced biostatistics topics that are widely used in health sciences research, including categorical data modeling procedures, methods for missing data, meta-analysis and others. Most topics will be covered on a conceptual/applied level by evaluating literature, exploring datasets and discussing interesting examples provided by instructor and/or guest faculty. Trainees will also bring examples of articles in their area of interest for discussion. The objective of this course is to expand upon biostatistics foundation provided in previous clinical research training courses so that students can: (1) understand and critically evaluate analytic methods used in the medical literature, (2) decide which methods may be appropriate for their own research projects, and, (3) communicate effectively with biostatistics collaborators to design, analyze and interpret data.

Prerequisites: HIP 511, 511A, 512 and 528.

Note: Class sessions held for three hours each, one day a week

Offered: Spring term.

HIP 530 Influence and Effective Communication for Leading Research Teams (2 credits) - Elective

Course Director: Nicole Steckler, PhD

Format: short lectures, discussion, self-assessment and group exercises, and experiential learning

Participants learn practical, influential leadership and communication skills. After completing this course, you will be able to: increase your awareness of the impact you have on others; invite and work with different academic and political perspectives; build strong collaborative relationships; mentor and coach others; use dialogue and “crucial conversations” to set direction and move your research team to action. Each session of this course combines invigorating, practical skill building with the opportunity for students to contribute personal experiences in leadership and to learn from other students in a structured collective learning process.

Note: This course meets for a total of four 4-hour sessions in two paired Friday afternoon/Saturday morning sessions.

Offered: Fall term

HIP 531 Project Management, (2 credits) - Elective

Course Director: Jeff Olmann, MEng, PMP

Format: short lectures, discussion, group exercises, and experiential learning

This course teaches project management from the standpoint of implementing a clinical research project. It emphasizes practical tools and techniques that students can use immediately on real projects. The class walks through the project life cycle in the same sequence that project leaders will use in the workplace, such as defining scope, planning a project, developing a timeline, executing and controlling project work, and closing a project. As part of the class, students will apply some of the project management techniques to real projects.

Note: This course meets for a total of four 4-hour sessions in two paired Friday afternoon/Saturday morning sessions.

Offered: Winter term

HIP 532 Understanding and Managing Academic Organizations (2 credits) - Elective

Course Director: Niki Steckler, PhD

Class sessions held for three hours each, one day a week

This course focuses on understanding and strengthening your current work relationships within the context of an academic health center. You will identify your strengths and blind spots as an academic leader and will learn how to “reframe” challenging situations to increase your understanding and consider alternative courses of action. This course will allow you to better understand the perspectives of different leaders (e.g. Dean, department chair, research administration) and allow you to work more effectively in this context.

Note: This course meets for a total of four 4-hour sessions on four Thursdays to be scheduled.

Offered: Spring term

HIP 533 Health Disparities and Community Based Research (2 credits) - Elective

Course Director: Somnath Saha, MD, MPH

Format: Didactic learning paired interactive discussion.

The goal of Health Disparities & Community Based Research is to educate students about: 1) disparities in health, health care, and research participation; 2) the social and cultural determinants of health and health disparities; 3) the potential for community engagement to enhance research participation and address health disparities; 4) challenges and opportunities in conducting research with and in communities; and 5) qualitative research methods commonly used in community-based research. Faculty with experience in clinical, health services, and community-based research, including qualitative methods, will discuss theoretical and practical aspects of these topics. The course will employ primarily didactic methods, but small group breakout sessions and interactive exercises will also be employed. Homework assignments will include directed reading and the development of a brief (2-page) protocol for a community-based research project.

Offered: Summer term

HIP 509: Scientific Review Committee Practicum, 3 months, (1.5 credits) - Elective

Course Director: Daniel Marks, MD

Format: Experiential learning

The goal of this module is to give trainees hands-on experience in the formal peer-review process of hypothesis-driven, investigator- initiated protocols through the General Clinical Research Center's Scientific Advisory Committee meetings. A GCRC protocol contains information on scientific rationale, experimental design, analytic methods, human subjects' issues and requests for specific GCRC resources. Trainees will meet with scientific reviewers and statisticians assigned to protocols to discuss issues regarding each protocol. Trainees will also submit their own written reviews to the committee and present at least two protocols at a SAC meeting.

Note: This elective module is limited to two or three selected trainees at one time.

Prerequisites: HIP 511 and 512

Offered: Fall, Winter and Spring terms

HIP 509: Systematic Review Practicum, 3 months, (variable credits) - Elective

Course Director: Varies

Format: Experiential learning

The goal of this practicum is to give trainees hands-on experience in the formal systematic review process by working with the Oregon Evidence-based Practice Center (EPC) on one of its USPSTF reviews. Trainees will work with a faculty mentor and the EPC team on all aspects of the systematic review process including: work plan creation and revision; search strategy planning; article abstraction; evidence synthesis; and drafting of a formal report manuscript. Trainees will be expected to attend EPC meetings and complete a significant amount of independent work for the review itself. Trainees will also take part in the final presentation of results at a national meeting, as well as submission of a manuscript for publication.

Prerequisites: HIP 511 and 512

Offered: Each term