

# The OHSU Human Investigations Program Course Catalog 2016-2017

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2016-2017



OREGON CLINICAL  
& TRANSLATIONAL  
*Research Institute*

The Human Investigations Program (HIP) offers graduate coursework leading to the Certificate in Human Investigations and the Master of Clinical Research (MCR). The HIP is supported by the Oregon Clinical and Translational Research Institute (OCTRI) which is funded by a U54 grant from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) and by contributions from the OHSU School of Medicine. The Graduate Council of OHSU School of Medicine provides oversight of the academic program.

The HIP curriculum consists of at least 24 courses including 9 *core* courses offered over a two-year period. The core courses are offered in a fixed sequence during the 2 years with opportunities for electives at varying times. Students will be offered graduate level academic credit for each course.

HIP offers two different educational tracks and a non-degree option:

- The certificate track includes the required core course modules in the first and second years, plus a choice of elective courses and a mentored experience resulting in a Capstone project such as a research proposal or publishable manuscript. Students completing this track will receive a Certificate in Human Investigations.
- The Master of Clinical Research (MCR) builds upon the certificate track. In addition to completing all required core courses and a Capstone project, trainees must complete approximately 20 elective credits drawn from the HIP curriculum, or graduate level courses from OHSU-PSU School of Public Health, biomedical informatics (BMI), and the basic science graduate program. Trainees completing this track will receive a Master's of Clinical Research.
- The non-degree option allows trainees to participate in specific courses in the HIP curriculum. This track does not include a mentored experience or Capstone and may fulfill a requirement in research training for some clinical fellowships. Courses can be taken for graduate level academic credit or for audit. Pre-registration is required and enrollment is based on space available. The course director will set the terms and conditions regarding participation for any given module. While attendance and homework requirements cannot be enforced while auditing, it is to the benefit of the individual to fully participate and attend each class.

See program web site ([www.ohsu.edu/hip](http://www.ohsu.edu/hip)) and student handbook for more information about program requirements.

**Tuition and Fees:**

For the Academic Year 2016-2017, required HIP core courses and some HIP elective courses are exempt from tuition. All other courses are charged tuition of \$500 per credit for HIP students in any track whether they are taking the course for academic credit or as an auditor. In addition, a nominal University Fee of \$193.00 per term applies. In the rare case that a HIP student takes 9 credits or more in a term, there are additional university fees and trainees should budget accordingly. See the Registrar's web page for more details on the current tuition and fees and a refund schedule.

Students graduating from the certificate or MCR programs are responsible for paying a graduation fee in their final term. In Academic Year 2016-2017, the graduation fee is \$50.0

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## Human Investigations Program Course Descriptions

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### **Academic Year 2016-2017**

*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 credit) –Required for Certificate and MCR***

*Course Director: Cynthia Morris, PhD, MPH*

*Format: Informational presentations, discussions, online lectures and resources*

The specific goal of Introduction to Clinical Research is to provide an early education to students in the essential skills and structure of clinical research and in the basic process of building a patient-oriented research study. Discussions will include the essential elements of a career in clinical research, opportunities for obtaining early career funding, and the importance of mentorship. Although didactic methods will be employed, there will also be an emphasis on introducing available resources to early career investigators. Subsequent courses will build on this foundation in specific areas (biostatistics, clinical research design, translational research, etc.).

**Note:** online

**Cost:** tuition-free

#### ***HIP 511, 512, 513 Clinical Research Design I, II and III (2 credits each) –Required for Certificate and MCR***

*Course Directors: Robert Cloutier, MD, MCR, John Stull, MD, MPH and Amy Laird, PhD*

*Format: Interactive classroom lectures and small group sessions*

This course sequence is the cornerstone of HIP. The goal is to educate trainees in the basic competencies of clinical research and in the basic process of building a patient-oriented research study. Interactive classroom lectures and discussions are conducted with emphasis on causal inference, measures of association, bias, confounding, and strengths and weaknesses of various study designs. 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. In the third term, the course provides in-depth study of research design with integration of biostatistical methods. More advanced topics include uses of more complex designs and modeling to control for confounding in experimental and observational studies. Evaluation of diagnostic testing is discussed, focusing on study design and implementation. Students will be asked to read current clinical literature to reflect on these themes.

**Offered:** sequentially Fall, Winter and Spring Terms;

**Cost:** tuition-free

**Note:** must be enrolled all 3 terms

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

Offered in conjunction with HIP 511, 512, 513 (Clinical Research Design I, II and III), this course offers a small group session experience in which trainees develop a hypothesis and clinical research study. Intertwined with lectures in HIP 511, 512, and 513, 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 come together as a complete grant proposal, with the exception of budget. Trainees in the small groups are expected to read and contribute to the development of the other proposals in the small group.

**Note:** HIP 511A must be taken in conjunction with HIP 511, 512 and 513, or with permission, the following year. No auditors allowed in HIP 511A.

**Offered:** Must be enrolled Fall, Winter and Spring terms

#### ***HIP 512A Biostatistics Lab, Online (1 credit) – Elective, Required for MCR***

*Course Director: Amy Laird, PhD*

*Format: Experiential learning, Online modules*

In this optional module, students will learn to use STATA to explore 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 511, 512, 513 series, or by permission

**Offered:** Fall, Winter, Spring, and Summer terms

***HIP 514 Molecular & Cellular Approaches to Disease, 8 weeks (2 credits) – Required for Certificate and MCR***

*Course Director: Cheryl Maslen, PhD*

*Format: Large group lectures and small discussion groups*

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 and translational study design. The lectures review important molecular, cellular and biological approaches frequently encountered with an emphasis on how these can be applied clinical studies. The objectives are to provide a fully integrated experience for both basic and clinician scientists in fundamentals of translational clinical research with examples from successful research projects. Three conceptually linked strategies are used: 1) lectures covering experimental approaches to translational projects, 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, use of animal models, receptor pharmacology, use of bioregistries, approaches to infectious diseases, mechanisms of treatment resistance, rare disorders and gene therapy, study design and statistical considerations.

**Offered:** Fall term

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

*Course Director: Kathryn Schuff, MD, MCR*

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

This course 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 course 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 Directors: Patricia Carney, PhD, Rachel Dresbeck, PhD, and Eric Johnson, PhD, MPH*

*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: Elizabeth Allen, MD, Robert Cloutier, MD, MCR and Beth Smith, DO*

*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, 512 and 513

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

***HIP 520 Medical Informatics, 7 weeks (2 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; 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.

**Note:** Subject to tuition

**Offered:** Summer term

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

*Course Director: 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.

**Prerequisites:** HIP 511, 512 and 513.

**Offered:** Summer term

***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, appropriate clinical research data management practices, and provides them with an understanding of database design. It is structured as a mixture of didactic and hands-on lab. 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

***HIP 526 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 Director: Marian McDonagh, PharmD,*

*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, 512 and 513.

**Offered:** Fall term

**Note:** Subject to tuition

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

*Course Directors: Miguel Marino, PhD*

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

This course, expanding on topics explored in the HIP 511/512/513 courses, will focus on multivariable methods widely used in clinical research: linear regression, logistic regression, survival analysis, and repeated measures analysis.

**Prerequisites:** HIP 511, 512, 513 and HIP 512A.

**Note:** Subject to tuition; 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 Directors: Miguel Marino, 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, 512, 513, HIP 512A and 528.

**Note:** Subject to tuition; Class sessions held for three *hours each, one day a week*

**Offered:** Spring term

***HIP 530 Leadership Skills in Team Science (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:** Subject to tuition; 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 Oltmann, 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:** Subject to tuition; 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

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

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:** Subject to tuition; This course meets for a total of four, 4-hour sessions on four Thursdays to be scheduled.

**Offered:** Spring term

***HIP 533 Community Based Research (2 credits) - Elective***

**Course Director:** Somnath Saha, MD, MPH

**Format:** Didactic learning paired interactive discussion.

The goal of Community Based Research is to educate students about: 1) the rationale and benefits of engaging the end-users of research in study design and conduct; 2) differing levels of community engagement and participation in research projects; 3) different roles that community stakeholders and members can play in research; 4) challenges and opportunities in conducting research with and in communities; and 5) logistical issues when involving community partners in research. Faculty with experience in clinical, health services, and community-based research will discuss theoretical and practical aspects of these topics. The course will employ didactic lectures, small group discussions and interactive exercises, and field trips. Homework assignments will include directed reading and the development of a brief (2-page) protocol for a community-based research project.

**Note:** Subject to tuition

**Offered:** Every other summer term – next offered Summer 2017

***HIP 534 Health Disparities Research (1 credit) – Elective***

**Course Director:** Somnath Saha, MD, MPH

**Format:** Didactic learning paired interactive discussion.

The goal of Health Disparities 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; and 3) challenges and opportunities in working with disadvantaged populations. Faculty with experience in clinical, health services, and disparities research 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 preparation for class discussions.

**Note:** Subject to tuition

**Offered:** Every other summer term – next offered Summer 2018

***HIP 535 Patient-Centered Outcomes and Comparative Effectiveness Research Principles (2 credits) – Elective***

**Course Directors:** Jeanne-Marie Guise, MD, MPH and Mark Helfand, MD, MS

**Format:** Didactic learning, interactive exercises, interactive discussion

Often there is a gap between the information that people need and the information that research provides. Patient-centered outcomes research (PCOR) seeks to identify and address these important clinical information gaps. PCOR engages the voice of patients, caregivers, and other stakeholders in research to produce results that help people make better-informed healthcare decisions and improve healthcare delivery and outcomes. This course explores the concepts that demarcate the field: generation and synthesis of evidence; PCOR principles in observational and interventional research; comparison of alternative methods; relevance of a patient-centered approach; and the science of making informed health care decisions. Scientists from across campus will discuss their work and experiences with PCOR and is intended for developing researchers to learn how people with productive labs and programs utilize PCOR.

**Prerequisites:** HIP 511, 512, and 513.

**Next Offered:** Winter 2018

***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 meet periodically with their mentor throughout their practicum as needed to plan and discuss their research. 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, 512, and 513; HIP 527

Offered: Each term with instructor approval