



Clinical Research Informatics

BMI-523

Fall 2019 3 Credits 09/23/2019 to 12/13/2019 Modified 08/26/2019

Description

This hybrid campus class will introduce the student to the principles of clinical research informatics. Topics include the design of clinical research, clinical trial administration, good clinical data management, clinical trial registration and publication, subject recruitment, use of administrative databases, registries and electronic health records in research, practice-based research networks, standards in terminology and messaging for clinical research, and research collaboration. Course activities will consist of readings of primary and summary literature, weekly graded assignments and activities, and a required face-to-face or video conferencing discussion once per week.

This syllabus is for BMI 523 OL F19, BMI 623 OL F19

Contact Information

Instructors:

Robert A. Schuff, MS
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Teaching Assistant:

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Meeting Times

5:00 – 6:30 PM (Pacific time) Mondays for 11 weeks, location: virtual meeting via Sakai for distance students. On-campus students are required to participate in BICC 513W. Students are required to attend at least 8 of the 11 class sessions in person or virtually. A computer with a browser, webcam and headphones with microphone are required for virtual attendance.

Materials

Course Goals

- To understand the types of clinical research being performed, along with the settings, activities and requirements for those types.
- To possess a foundational understanding of the legal and ethical issues of clinical research.

To learn the principles of good data capture and management.

- To know the types of information systems that are used in clinical research including clinical trial administration.
- To understand the emerging requirements for clinical trial registration and reporting.
- To understand how data collected in clinical care can be used for research and its advantages and disadvantages.
- To understand how data used for administrative purposes can be used for research and its advantages and disadvantages.
- To know basics of the data and messaging standards that are emerging for clinical research.
- To learn about practice-based research and understand its scope and limitations.
- To learn about new trends in research collaboration and recruitment and the informatics tools that are enabling them.

Course Competencies, Outcomes, and Objectives

Assessment

Grading:

This is a 3 credit, graded class. Grades are based on the following:

- Assignments: 40%
- Quizzes: 30%
- Class participation: 30%

The lowest score in each of the above categories will be dropped.

Please note that because participation plays a vital role in this class, you must attend at least 8 of 11 sessions. If you do not attend at least 8 sessions you will not pass the course. Also please note that you will not receive a participation credit on days when you do not attend, even if your absence is excused.

Doctoral students will also be expected to complete a term paper, which they should discuss with the instructors. This paper must be 8-10 double-spaced pages with exploration of a specific CRI topic, and will count for half of the assignment points.

Letter grades will be assigned as follows:

92-100 A
90-91 A-
88-89 B+
82-87 B
80-81 B-
78-79 C+
72-77 C
70-71 C-
Below 70 F

Course & Instructor Evaluations

Schedule

Each week for 11 weeks, students will meet in person or virtually for class. The first week will be an introduction to the course only.

Each week's assignments will be posted the prior Monday and will consist of a summary of one or more topics, required readings, online video of demos (some weeks) and an assignment. The assignment must be completed online prior to the class at which the topic will be discussed. Please be sure to check the assignments online on Mondays for any recent updates. Tentatively:

Week	Topic	Lead Instructor
1 9/23	Introduction	Rob Schuff Nicole Weiskopf
2 9/30	Clinical and Translational Research Informatics Fundamentals	Rob Schuff Nicole Weiskopf
3 10/7	Database Fundamentals	Rob Schuff
4 10/14	Secondary Use of Clinical Data in Research	Nicole Weiskopf
5 10/21	Clinical Research Data Management	Rob Schuff
6 10/28	Standards in Clinical Research Informatics	Rob Schuff
7 11/4	Clinical Research Administration Systems	TBD
8 11/11	Recruitment and Cohort Identification	Rob Schuff Nicole Weiskopf
9 11/18	Other Sources of Data in Research	TBD
10 11/25	Patient-Generated Data in Research	Nicole Weiskopf
11 12/2	Rigor and Reproducibility	Nicole Weiskopf

Grading Criteria, Academic Standards, & Release of Final Grades:

Graduate Studies in the OHSU School of Medicine is committed to providing grades to students in a timely manner. Course instructors will provide students with information in writing at the beginning of each course that describes the grading policies and procedures including but not limited to evaluation criteria, expected time needed to grade individual student examinations and type of feedback they will provide.

All coursework applied towards degree requirements must meet the minimum cumulative grade point average of at least 3.0.

Refer to the [School of Medicine Graduate Studies Forms & Policies \(https://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/graduate-studies/admin-resources.cfm\)](https://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/graduate-studies/admin-resources.cfm) for withdraw, incomplete, and in-progress grading standards. Final course grades will be posted with the OHSU Registrar the Monday following the last day of the term. On those occasions when a grade has not been submitted by the deadline, the following procedure shall be followed:

1. The Department*/Program** Coordinator will immediately contact the Instructor requesting the missing grade, with a copy to the Program Director and Registrar.
2. If the grade is still overdue by the end of next week, the Department*/Program** Coordinator will email the Department Chair directly, with a copy to the Instructor and Program Director requesting resolution of the missing grade.
3. If, after an additional week the grade is still outstanding, the student or Department*/Program** Coordinator may petition the Office of Graduate Studies for final resolution.

*For courses that are run by a specific department.

**For the conjoined courses (course number is preceded by CON) that are run by Graduate Studies.

Graduate Studies Guidelines:

Students are responsible for following all OHSU School of Medicine, Graduate Studies, and program/department guidelines & policies. For more information, please [visit here \(https://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/graduate-studies/admin-resources.cfm\)](https://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/graduate-studies/admin-resources.cfm). For program/department guidelines & policies, please inquiry with the program/department director and/or coordinator.

School of Medicine Conduct Policy (housed under the graduate studies guidelines section)

Students are responsible for their own academic work. Students are expected to have read and practice principles of academic honesty, as presented in the [Graduate Studies Student Handbook. \(http://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/graduate-studies/admin-resources.cfm\)](http://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/graduate-studies/admin-resources.cfm)

The School of Medicine reserves the privilege of retaining only those students who, in the judgement of the faculty, satisfy the requirements of scholarship and clinical performance necessary to maintain the highest standards. The Student Handbook has information about academic standards and probation and dismissal policies.

Graduate Studies Copyright Information

Every reasonable effort has been made to protect the copyright requirements of materials used in this course. Class participants are warned not to copy, audio, or videotape in violation of copyright laws. Journal articles will be kept on reserve at the library or online for student access. Copyright law does allow for making one personal copy of each article from the original article. This limit also applies to electronic sources.

Graduate Studies Inclement Weather Procedures

Inclement weather procedures can be [found here \(http://www.ohsu.edu/xd/about/visiting/weather/index.cfm\)](http://www.ohsu.edu/xd/about/visiting/weather/index.cfm). In the case of inclement weather, the faculty member will email or place a voice-mail greeting on her/his office telephone number by 6:00am on the day of the clinical or class to give instructions to students about the class schedule.

School Competencies

OHSU Competencies

OHSU Graduation Core Competencies

1. Professional Knowledge and Skills

Demonstrate competence in the core knowledge, skills, and practices as defined by degree programs and relevant professional licensing and credentialing boards.

2. Reasoning and Judgement

Demonstrate the ability to identify and define problems, critically compare options, make timely decisions or recommendations, identify uncertainties, and use findings to improve outcomes in light of evolving evidence.

3. Evidence-Based Practice and Research

Demonstrate the ability to access, evaluate, and apply relevant science knowledge to support evidence-based health care, disease prevention, health promotion and discovery.

4. Lifelong Learning

Demonstrate the ability to recognize gaps in knowledge and experience through informed self-assessment and reflective practices, and take actions to address those gaps.

5. Communication

Demonstrate active listening and oral and written communication skills with diverse individuals, communities, and colleagues to ensure effective, culturally appropriate exchange of information.

6. Professionalism and Ethics

Demonstrate integrity, honesty, knowledge of ethical principles and the standards of professional conduct, and the ability to apply ethical principles in clinical care, research, education or community service.

7. Teamwork

Demonstrate the abilities required to foster and work effectively within collaborative, team-based environments.

8. Safety and Quality Improvement

Demonstrate the ability to identify situations that compromise safety and participate in risk reduction and continuous quality improvement.

9. Systems

Demonstrate an appropriate understanding of evolving health care systems, health and science policy, and resource allocation in order to optimize human health and scientific discovery.

10. Patient/Client-Centered Care

Additionally, clinical degree program graduates will be able to...

Demonstrate the ability to collaborate with diverse individuals, families, and communities to provide quality care that is respectful of and responsive to their preferences, needs, attitudes, beliefs and values.

Statement Regarding Students with Disabilities:

OHSU is committed to inclusive and accessible learning environments in compliance with federal and state law. If you have a disability or think you may have a disability (mental health, attention-related, learning, vision, hearing, physical or health impacts) contact the Office for Student Access at (503) 494-0082 or [OHSU Student Access \(mailto:studentaccess@ohsu.edu\)](mailto:studentaccess@ohsu.edu) to have a confidential conversation about academic accommodations. Information is also available at [Student Access Website \(http://www.ohsu.edu/student-access\)](http://www.ohsu.edu/student-access). Because accommodations may take time to implement and cannot be applied retroactively, it is important to have this discussion as soon as possible.

Portland State students also have similar resources available via the PSU Disability Resource Center (website <http://www.pdx.edu/drc> (<http://www.pdx.edu/drc>)). Please contact the DRC at tel. (503) 725-4150 or email at drc@pdx.edu (<mailto:drc@pdx.edu>)

Student Evaluation of Courses:

Course evaluation results are extremely important and used to help improve courses and the learning experience of future students. Responses will always remain anonymous and will only be available to instructors after grades have been posted. The results of scaled questions and comments go to both the instructor and their unit head/supervisor. Refer to Student Evaluation of Courses and Instructional Effectiveness, *[Policy No. 02-50-035 \(https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/chapter-2-student-affairs/ohsu-policy-02-50-035.cfm\)](https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/chapter-2-student-affairs/ohsu-policy-02-50-035.cfm).

*To access the OHSU Student Evaluation of Courses and Instructional Effectiveness Policy, you must log into the [OHSU O2 website \(https://o2.ohsu.edu/\)](https://o2.ohsu.edu/).

Copyright Information:

Copyright laws and fair use policies protect the rights of those who have produced the material. The copy in this course has been provided for private study, scholarship, or research. Other uses may require permission from the copyright holder. The user of this work is responsible for adhering to copyright law of the U.S. (Title 17, U.S. Code). To help you familiarize yourself with copyright and fair use policies, the University encourages you to visit its [Copyright Web Page \(https://www.ohsu.edu/xd/education/library/services/copyright/\)](https://www.ohsu.edu/xd/education/library/services/copyright/)

Sakai course web sites contain material protected by copyrights held by the instructor, other individuals or institutions. Such material is used for educational purposes in accord with copyright law and/or with permission given by the owners of the original material. You may download one copy of the materials on any single computer for non-commercial, personal, or educational purposes only, provided that you (1) do not modify it, (2) use it only for the duration of this course, and (3) include both this notice and any copyright notice originally included with the material. Beyond this use, no material from the course web site may be copied, reproduced, re-published, uploaded, posted, transmitted, or distributed in any way without the permission of the original copyright holder. The instructor assumes no responsibility for individuals who improperly use copyrighted material placed on the web site.

Syllabi Changes and Retention:

Syllabi are considered to be a learning agreement between students and the faculty of record. Information contained in syllabi, other than the minimum requirements, may be subject to change as deemed appropriate by the faculty of record in concurrence with the academic program and the Office of the Provost. Refer to the *[Course Syllabi Policy, 02-50-050. \(https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/chapter-2-student-affairs/ohsu-policy-02-50-050.cfm\)](https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/chapter-2-student-affairs/ohsu-policy-02-50-050.cfm)

*To access the OHSU Course Syllabus Policy, you must log into the [OHSU O2 website \(https://o2.ohsu.edu/\)](https://o2.ohsu.edu/).

Commitment to Diversity & Inclusion:

OHSU is committed to creating and fostering a learning and working environment based on open communication and mutual respect. If you encounter sexual harassment, sexual misconduct, sexual assault, or discrimination based on race, color, religion, age, national origin, veteran's status, ancestry, sex, marital status, pregnancy or parenting status, sexual orientation, gender

identity, disability or any other protected status please contact the Affirmative Action and Equal Opportunity Department at 503-494-5148 or aao@ohsu.edu (<mailto:aao@ohsu.edu>). Inquiries about Title IX compliance or sex/gender discrimination and harassment may be directed to the OHSU Title IX Coordinator at 503-494-0258 or titleix@ohsu.edu. (<mailto:titleix@ohsu.edu>)

Modified Operations, Policy 01-40-010:

Students should review the Student Portal, O2, or call [OHSU's weather alert](https://www.ohsu.edu/xd/about/visiting/weather/) (<https://www.ohsu.edu/xd/about/visiting/weather/>) line at 503-494-9021 for the most up-to-date information on OHSU-wide modified operations which include but are not limited to delays or closures for inclement weather. For specific campus information, outside of Portland, check the following sites:

- Ashland Campus: [SOU Inclement Weather](https://inside.sou.edu/hrs/inclement-weather.html) (<https://inside.sou.edu/hrs/inclement-weather.html>)
- Klamath Fall Campus: [OIT Inclement Weather](http://www.oit.edu/inclement-weather) (<http://www.oit.edu/inclement-weather>)
- La Grande Campus: [EOU Inclement Weather Update](https://www.eou.edu/news-press/campus-status-and-weather-updates/) (<https://www.eou.edu/news-press/campus-status-and-weather-updates/>)
- Monmouth Campus: [WOU Inclement Weather](http://www.wou.edu/hr/resources/policies/campus-inclement-weather-notice) (<http://www.wou.edu/hr/resources/policies/campus-inclement-weather-notice>)

OHSU Learning Resources Available to Students*:

Registrar's Office

Mackenzie Hall, Rm. 1120

503-494-7800; [Email the Registrar](mailto:regohsu@ohsu.edu) (<mailto:regohsu@ohsu.edu>)

Student Registration Information:

[To Register for Classes](http://www.ohsu.edu/xd/education/student-services/registrar/registration-information/index.cfm) (<http://www.ohsu.edu/xd/education/student-services/registrar/registration-information/index.cfm>)

OHSU ITG Help Desk

Regular staff hours are 6 a.m. to 6 p.m., Monday through Friday, but phones are answered seven days a week, 24 hours a day. Call 503 494-2222.

Teaching and Learning Center

Academic Support Counseling and Sakai Course Management System, please contact the TLC Help Desk at 877-972-5249 or email [Sakai Help Desk](mailto:sakai@ohsu.edu) (<mailto:sakai@ohsu.edu>)

Concourse Syllabus Management

For help with accessing your Concourse Syllabus: Please contact the Sakai help Desk for all other Concourse inquiries please visit the [Concourse Tutorial Website](https://o2.ohsu.edu/educational-improvement-and-innovation/concourse-syllabus-management.cfm) (<https://o2.ohsu.edu/educational-improvement-and-innovation/concourse-syllabus-management.cfm>) or please contact the Mark Rivera at rivermar@ohsu.edu (<mailto:rivermar@ohsu.edu>) or call 503-494-0934

Office of Public Safety

- Emergency on Campus: 503-494-4444 (Portland)
- Non-emergency: 503-494-7744; [Contact Public Safety](mailto:pubsafe@ohsu.edu) (<mailto:pubsafe@ohsu.edu>)

Joseph B. Trainer Health & Wellness Center

Baird Hall, Rm. 18 (Primary Care) and Rm. 6 (Behavioral Health)

503-494-8665; For urgent care after hours, 503-494-8311 and ask for the Nurse on call.

[Wellness Center Information](mailto:askjbthealth@ohsu.edu) (<mailto:askjbthealth@ohsu.edu>)

[Wellness Center Website](http://www.ohsu.edu/xd/education/student-services/joseph-trainer-health-wellness-center/) (<http://www.ohsu.edu/xd/education/student-services/joseph-trainer-health-wellness-center/>)

**Exceptions include Public Health students who have selected PSU as their primary providers and students whose home campus is a satellite campus or online. If your home institution is not on the Portland campus, contact your home institution student support services for more information.*

Ombudsman Office

Gaines Hall, Rm. 117

707 SW Gaines Street, Portland, OR 97239

503-494-5397; [Contact Ombudsman](mailto:graybill@ohsu.edu) (<mailto:graybill@ohsu.edu>); [Ombudsman Website](https://www.ohsu.edu/xd/about/services/ombudsman/) (<https://www.ohsu.edu/xd/about/services/ombudsman/>)

Library: Biomedical Information Communication Center

[BICC Library Hours of Operation \(http://www.ohsu.edu/xd/education/library/about/hours.cfm\)](http://www.ohsu.edu/xd/education/library/about/hours.cfm)

Additional Items
