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. Doctoral students will have an additional term paper required.

Instructors:

Robert A. Schuff, MS  
Office: 503-494-5654  
schuffr@ohsu.edu

Nicole Weiskopf, PhD  
Office: 503-494-3708  
weiskopf@ohsu.edu

Teaching Assistant:

Kate Fultz Hollis  
Office: 310-429-0346  
fultzholl@ohsu.edu

Class 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.

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

Grading Policy:
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.

Class grades are due to the Registrar by the Friday following the week of finals. However, on those occasions when a grade has not been submitted by the deadline, the following procedure shall be followed:

1) The Department\textsuperscript{1}/Program Coordinator\textsuperscript{2} 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\textsuperscript{1}/Program Coordinator\textsuperscript{2} 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\textsuperscript{1}/Program Coordinator\textsuperscript{2} may petition the Office of Graduate students for final resolution.

Objectives:

- 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.

**Professional Conduct Policy:**
The professional conduct policy of the Graduate Studies Program can be found at [http://www.ohsu.edu/xd/about/services/integrity/policies/upload/2011OHSU-Code-of-Conduct.pdf](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/2011OHSU-Code-of-Conduct.pdf). The term paper must be solely the work of the enrolled student. A violation will result in zero points for the paper as well as referral to the professional conduct committee of DMICE.

In an effort to uphold the principles and practice of academic honesty, faculty members at OHSU may use originality checking systems such as Turnitin to compare a student’s submitted work against multiple sources.

To protect student privacy in this process, it will be necessary to remove all personal information, i.e. student name, email address, student u-number, or any other personal information, from documents BEFORE submission.

See [http://www.ohsu.edu/xd/education/teaching-and-learning-center/for-students/index.cfm](http://www.ohsu.edu/xd/education/teaching-and-learning-center/for-students/index.cfm) for more information on citing sources and recognizing plagiarism.

**Syllabus Statement Regarding Disability Services**
OHSU is committed to providing equal access to qualified students who experience a disability in compliance with Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act (ADA) of 1990, and the ADA Amendments Act (ADA-AA) of 2008. If you have a disability or think you may have a disability (physical, sensory, chronic health, psychological or learning) please contact the Office for Student Access at (503) 494-0082 or studentaccess@ohsu.edu to discuss eligibility for academic accommodations. Information is also available at [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. All information regarding a student’s disability is kept in accordance with relevant state and federal laws.
Commitment to Equity and Inclusion
Oregon Health & Science University 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 or ancestry, veteran or military status, 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 aaeo@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.

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.

To comply with the fair use doctrine of the US copyright law, Sakai course sites close three weeks after grades are posted with the Registrar. Please be sure to download all course material you wish to keep before this time as you will have no further access to your courses.

Use of Sakai
This course will have an online component, which can be accessed through Sakai, OHSU’s online course management system. For any technical questions or if you need help logging in, please contact the Sakai Help Desk.

   Hours: Sakai Help Desk is available Mon – Fri, 8 am – 9 pm and weekends 12 pm – 5 pm, Pacific Time.  
   Contact Information:  
   (Toll-free) 877-972-5249  
   (Web) http://atech.ohsu.edu/help  
   (Email) sakai@ohsu.edu

DMICE Communication Policy
1. If the syllabus directs the student to contact the TA before contacting the instructor, the student should do so. Otherwise, the student should contact the instructor and allow 2 business days (not including weekends) for a response.
2. If the student does not receive a response from the instructor within 2 business days, s/he should contact the TA (if there is one). When contacting the TA s/he should cc the instructor and Diane Doctor at doctord@ohsu.edu.
3. If a student does not receive a response from the TA within 1 business day (not including weekends), s/he should contact Diane Doctor at doctord@ohsu.edu and cc the instructor and the TA.
4. If Diane does not reply within 1 business day (not including weekends), the student should contact Andrea Ilg at ilgan@ohsu.edu.
5. Students having difficulties with Sakai should contact the Sakai Help Desk at sakai@ohsu.edu or at (877) 972-5249. Sakai help is available M-F from 8am to 10-pm and weekends from Noon to 5pm. Do not contact the instructor.

6. Please use professional etiquette when communicating with peers and the instructor. This means avoiding aggressive or offensive language, showing respect for others’ opinions and positions, and conducting yourself as if you were face to face with them. Please pay special attention to etiquette in class forums and when using email. If you notice someone violating this policy, please make the instructor and TA aware of the problem.

Syllabus (Tentative):
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:

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic</th>
<th>Lead Instructor</th>
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<tbody>
<tr>
<td>1</td>
<td>9/24 Introduction</td>
<td>Rob Schuff</td>
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<td></td>
<td></td>
<td>Nicole Weiskopf</td>
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<tr>
<td>2</td>
<td>10/1 Clinical &amp; Translational Research Informatics Fundamentals</td>
<td>Rob Schuff</td>
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<td>Nicole Weiskopf</td>
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<tr>
<td>3</td>
<td>10/8 Database Fundamentals</td>
<td>Rob Schuff</td>
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<tr>
<td>4</td>
<td>10/15 Secondary Use of Clinical Data in Research</td>
<td>Nicole Weiskopf</td>
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<tr>
<td>5</td>
<td>10/22 Clinical Research Data Management</td>
<td>Rob Schuff</td>
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<tr>
<td>6</td>
<td>10/29 Standards in Clinical Research Informatics</td>
<td>Rob Schuff</td>
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<td>7</td>
<td>11/5 Clinical Research Administration Systems</td>
<td>TBD</td>
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<td>8</td>
<td>11/12 Recruitment and Cohort Identification</td>
<td>Rob Schuff</td>
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<td>Nicole Weiskopf</td>
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<td>9</td>
<td>11/19 Other Sources of Data in Research</td>
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<tr>
<td>10</td>
<td>11/26 Patient-Generated Data in Research</td>
<td>Nicole Weiskopf</td>
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<tr>
<td>11</td>
<td>12/3 Rigor and Reproducibility</td>
<td>Nicole Weiskopf</td>
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