

## **BMI 523/623: Clinical Research Informatics**

### **Fall term, 2014**

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.

#### **Instructor:**

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#### **Required Textbook:**

Clinical Research Informatics  
Richesson, Rachel L and Andrews, James E. (Eds).  
2012 Springer Health Informatics, ISBN 978-1-84882-447-8

Note: This textbook may be available electronically through OHSU's library.

#### **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 513. 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:**

3 credits, graded class based on the following:  
weekly assignments and activities 70%  
participation in class discussions, 30% (students must attend at least 8 of 11 classes in order to pass the course)

The term paper for Doctoral students will be 8-10 double-spaced pages with exploration of a specific CRI topic.

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<sup>1</sup> /Program Coordinator<sup>2</sup> 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<sup>1</sup> /Program Coordinator<sup>2</sup> 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<sup>1</sup> /Program Coordinator<sup>2</sup> may petition the Office of Graduate students for final resolution.

<sup>1</sup> For courses that are run by a specific department.

<sup>2</sup> For the conjoined courses (course number is preceded by CON\_ that are run by Graduate Studies.

### **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 which are enabling them.

### **Professional Conduct Policy:**

The professional conduct policy of the Graduate Studies Program can be found at <http://davinci.ohsu.edu/~loganju/BMI544/profconductpolicy.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> for more information on citing sources and recognizing plagiarism.

### **Student Access:**

OHSU is committed to providing equal access to qualified students with disabilities. Student Access determines and facilitates reasonable accommodations, including academic adjustments and auxiliary aids, for students with documented disabilities. A qualified student with a disability is a person who meets the academic and technical standards requisite to admission or participation in a particular program of study. As defined by the Americans with Disability Act (ADA), a person with a disability has a physical or mental impairment that substantially limits one or more major life activities of the individual. This may include, but is not limited to, physical conditions, chronic health issues, sensory impairments, mental health conditions, learning disabilities and ADHD. Student Access works with students with disabilities from all of OHSU's educational programs and at each campus.

Each school has an assigned Program Accommodation Liaison (PAL), who acts as an "in-house" resource for students and faculty concerning access issues for students with disabilities. The PAL works in collaboration with Student Access to implement recommended accommodations for students with disabilities.

It is recommended that you contact Student Access to consult about possible accommodations if you a) received disability accommodations in the past, b) begin experiencing academic difficulties, and/or c) are given a new diagnosis from your healthcare provider.

Learn more about Student Access:

Phone: 503 494-0082

Email: [studentaccess@ohsu.edu](mailto:studentaccess@ohsu.edu)

Website: [www.ohsu.edu/student-access](http://www.ohsu.edu/student-access)

### **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 – 10 pm and weekends and holidays 12 pm – 5 pm

Contact Information:

(Toll-free) 877-972-5249

(Web) <http://atech.ohsu.edu/help>

(Email) [sakai@ohsu.edu](mailto: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](mailto: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](mailto: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](mailto:ilgan@ohsu.edu).
5. Students having difficulties with Sakai should contact the Sakai Help Desk at [sakai@ohsu.edu](mailto:sakai@ohsu.edu) or at (877) 972-5249. Sakai help is available M-F from 8am to 10pm and weekends from Noon to 5pm. Do not contact the instructor.

### 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. Assignments for the next week will be posted each 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 next class at which the topic will be discussed.

| Week | Topics posted to be discussed the following week                                                     | Textbook chapter        |
|------|------------------------------------------------------------------------------------------------------|-------------------------|
| 1    | Clinical and Translational Research: research designs and activities (for students with non-research | 3 (1, 2 and 4 optional) |

|    |                                                                                                               |                                |
|----|---------------------------------------------------------------------------------------------------------------|--------------------------------|
|    | backgrounds)<br>OR<br>Computing fundamentals (for students with research backgrounds)                         | OR<br>2 (1, 3, and 4 optional) |
| 2  | Clinical data management                                                                                      | 10                             |
| 3  | Database fundamentals                                                                                         |                                |
| 4  | Use of EHRs, registry and administrative data in clinical research                                            | 13, 16, 17                     |
| 5  | Data sources for clinical research:<br>Biobanks and LIMS<br>Biosignals and Imaging<br>Genomics and Proteomics | 7, 12                          |
| 6  | Emerging standards in clinical research informatics                                                           | 9, 14, 18                      |
| 7  | Clinical research management systems                                                                          | 8                              |
| 8  | Clinical trial registration and publication                                                                   | 20                             |
| 9  | Recruitment in clinical research<br>Collaboration in clinical research                                        | 5                              |
| 10 | Special topics:<br>Pharmacovigilance<br>Research networks                                                     | 6, 11, 19 (15, 21 optional)    |