BMI 523/623: Clinical Research Informatics
Fall term, 2015

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:

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Required Textbook:

Clinical Research Informatics

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

Class times:

There will be a synchronous virtual meeting via Sakai for all students 5:00 – 6:30 PM (Pacific time) Mondays for 10 weeks. There will be no class Monday, Sept. 28, 2015 because of the OHSU new student orientation that day. On-campus students are required to participate in BICC 513. Distance students will participate virtually using Virtual Meeting in Sakai. They will dial in to an 800 number for audio participation. Students are required to attend at least 8 of the 10 class sessions in person or virtually. A computer with a webcam, an internet connection and a telephone are required for virtual attendance. A land line is preferred to minimize background noise.

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\(^1\)/Program Coordinator\(^2\) 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\(^1\)/Program
Coordinator\(^2\) 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\(^1\)
/Program Coordinator\(^2\) may petition the Office of Graduate students for final resolution.

\(^1\) For courses that are run by a specific department.
\(^2\) 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 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, learning, or other) 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. 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.

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 from 12 pm – 5 pm (closed on official OHSU holidays).

Contact Information:
(Toll-free) 877-972-5249
(Web) [http://atech.ohsu.edu/help](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 9pm and weekends from Noon to 5pm (closed on official OHSU holidays). 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. Please be sure to check the assignments online on Mondays for any recent updates. Tentatively:

<table>
<thead>
<tr>
<th>Week</th>
<th>Topics posted to be discussed the following week</th>
<th>Textbook chapter</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Clinical and Translational Research: research designs and activities (for students with non-research)</td>
<td>3 (1, 2 and 4 optional)</td>
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<tr>
<td></td>
<td>Course Title</td>
<td>Options</td>
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<tr>
<td>2</td>
<td>Clinical data management</td>
<td>10</td>
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<tr>
<td>3</td>
<td>Database fundamentals</td>
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<td>4</td>
<td>Use of EHRs, registry and administrative data in clinical research</td>
<td>13, 16, 17</td>
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<tr>
<td>5</td>
<td>Data sources for clinical research: Biobanks and LIMS Biosignals and Imaging Genomics and Proteomics</td>
<td>7, 12</td>
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<tr>
<td>6</td>
<td>Emerging standards in clinical research informatics</td>
<td>9, 14, 18</td>
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<tr>
<td>7</td>
<td>Clinical research management systems</td>
<td>8</td>
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<td>8</td>
<td>Clinical trial registration and publication</td>
<td>20</td>
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<tr>
<td>9</td>
<td>Recruitment in clinical research Collaboration in clinical research</td>
<td>5</td>
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<tr>
<td>10</td>
<td>Special topics: Pharmacovigilance Research networks</td>
<td>6, 11, 19 (15, 21 optional)</td>
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