Syllabus
Data Management (CLRE-255), 2 Units

Fall 2020

Course instructor
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Course TA(s)
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Course Description
This course will provide you with an orientation to information management, and covers key issues regarding data acquisition, storage, data interoperability to support clinical research and clinical trials. You will also become familiar with technology used to capture, store, and display/analyze clinical trial data. This includes traditional systems, cloud computing, mobile technology, and wearable sensors.

Course Organization (Method of instruction)
The course will meet eight (8) times, two (2) hours each meeting. This course section will total fourteen (14) one-hour lectures, plus two (2) one-hour hands-on applied lab exercises. Prior to each lesson, students should have completed the background reading for that week.

Class Location
Class will be online only. Zoom link to be provided in Canvas calendar.
Class Meeting Time
Via Zoom only. Wednesdays 4:00pm-6:00pm
https://uchealth.zoom.us/j/945310330 (Links to an external site.)

Fall Quarter:
First day of class for CLRE255: **Wednesday, April 1, 2020**
Last day of class for CLRE255: **Wednesday, June 10, 2020**
Final Exam: **Wednesday, June 10, 2020, 4pm-6pm**
Final Project: **Data Management Plan, Due by June 3, 2020**

Course Objectives
Following completion of this course, students should be able to:

- Describe traditional as well as emerging clinical trial models, such as adaptive trials and master protocols
- Define data management in the context of clinical research
- Describe best practices in research informatics
- Describe cloud computing and cloud based services relevant to clinical research data management
- Define the components of a robust data security plan, including both federal and California specific health privacy laws.
- Define the components of the necessity for data and safety monitoring plans.
- Develop protocols utilizing computer technology for data acquisition and management
- Describe the role of health information technology standards in provisioning information infrastructure to support clinical trials
- Describe the essential functions of the electronic health record (EHR) and typical issues arising from the use of the EHR to support clinical research
- Describe Real World Evidence (RWE) and Real World Data (RWD)
- Describe basic sensors and wearables functions and their relevance to clinical trials

Prerequisites and Preparation – enrollment in a health profession advanced degree program
Course Materials/Resources
Textbook: “Clinical Research Informatics,” by Rachel Richesson and James Andrews. The book will be provided by the program as a digital copy in the course Canvas site.

Computer software:
Web browser

Course Components

- Lectures
- Obtaining permission to use MIMIC3 database
- Applied Exercises (2 of them)
- Final Exam
- Data Management Plan - Project

Exams/Final projects

- Final Exam (open book)
- Final Project – Data Management Plan

Grading Policy
Course Evaluation: Class Participation, 2 Applied Exercises, Final Exam (open book), and Final Project (Data Management Plan). Grades are posted on TritonLink - Canvas (if you are matriculated- in MAS Program), on MyExtension (if you are non-matriculated, concurrent enrollment)

A final grade of B minus or higher required to pass

Grades are based on points and the letter grades are given as follows:

- Class participation 40% (lecture attendance= 30% + 2 applied labs @5% each)
  - Attendance (per CREST policy --3 unexcused result in a failing grade) 30%
  - Participation in each of 2 Applied Labs @5% each = 10%
- MIMIC3 CITI training and Data Use Agreement (required by session 4): 10%
- Data Management Plan - Project 20%
  - Grading based on
    - Completeness
    - Relevance of data management plan to research study
    - Quality of writing
Course Policy and Expectations (classroom rules of conduct)

- Attendance Policy: CREST/MAS program policy requires a minimal attendance of 70%, seven of the ten sessions. Please, be sure not to exceed 3 absences as you will have to drop and repeat the course. Coming to class 20 minutes after the class starts also counts as an absence so, please be on time.
- Academic Integrity (Plagiarism): http://academicintegrity.ucsd.edu/Links to an external site.
- Late work submission policy
  - Five percent penalty per day for late submission, unless prior arrangements are made.

Communication with lecturers: Through Canvas (email) or text messaging.

Student Evaluation of Course and Faculty

Course and faculty evaluations provide important feedback to instructors to improve course content and teaching methodology. Teaching evaluations are also an important factor in faculty advancement, merit and promotion. This is also part of developing professional conduct and behavior.

Technical Requirements:

- Internet connection and computer
Accommodations: If you have a disability that may impact your academic performance, you may request accommodations by submitting documentation to: https://students.ucsd.edu/well-being/disability-services/Links to an external site.