Syllabus
Data Management (CLRE-255), 2 Units
Fall 2019

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 nine (11) times, two (2) hours each meeting. This course section will total fourteen (15) one-hour lectures plus three(3) one-hour applied exercises. Prior to each lesson, students should have completed the background reading for that week in Clinical Research Computing: A Practitioner’s Handbook and articles posted in TritonEd for the lesson. Office hours are 30 minutes after lecture as needed.

Class Location
Class held off-campus at UCSD Extension’s University City Center
6256 Greenwich Dr., San Diego, CA 92122 Suite 150, Room 112

Class Meeting Time
Wednesdays 4:00pm-5:50pm

Spring Quarter:
First day of class for CLRE255: Wednesday, April 3 2019
Last day of class for CLRE255: Monday, June 5, 2019
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
The book will be provided by the program.

Computer software:
You will be using specialized software for the applied exercise sessions. Each student will need to have a laptop computer. Software required for the lab exercises will be provided.

Online resources: (TritonEd: https://tritoned.ucsd.edu) For each lesson, a slide presentation of the lecture, the in-class homework description, and supplementary reading can be found as PDF files in the Content section of the course on TritonEd.
Course Components
- Lectures
- Midterm and Final Exam
- Data Management Plan - Project
- Applied Exercises (3 of them)

Exams/Final projects
- Interim and Final Project

Grading Policy
Course Evaluation: Class Participation, Midterm and Final Exam (non-comprehensive), and Final Project (Data Management Plan). Grades are posted on TritonLink (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%
  - Attendance (per CREST policy --3 unexcused result in a failing grade) 10%
  - Participation in each of 3 Applied Labs @10% each = 30%
- Data Management Plan - Project 20%
  - Grading based on
    - Completeness
    - Relevance of data management plan to research study
    - Quality of writing
- Midterm Exam: 15%
- Final Exam (non-comprehensive): 15%
- MIMIC3 CITI training and Data Use Agreement (required by session 4): 10%

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<td>A+</td>
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Course Policy and Expectations (classroom rules of conduct)

- Attendance Policy: Suggested posting on the syllabus and on TritonEd: 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.
- How do you handle technical devices?
  - Laptops can be used during lectures for note taking
  - Cell phones should be turned off. If you are on call silence your phone.
- Academic Integrity (Plagiarism): [http://academicintegrity.ucsd.edu/](http://academicintegrity.ucsd.edu/)
- Late work submission policy
  - Five percent penalty per day for late submission, unless prior arrangements are made.

Communication with lecturers: The best way to reach us is via email. We will try to respond within 24 hours.

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. To facilitate ease of completion of evaluations an electronic format has been implemented in Survey Monkey. Please see the TritonEd page for the link.

Technical Requirements:
- Students are required to bring their laptop with them for the Applied Exercise sessions

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/](https://students.ucsd.edu/well-being/disability-services/)