

MEDI 5074: Data Management, Quality Control and Regulatory Issues

Spring 2018

CLASS DAYS and TIME: Tuesdays, 3:00 – 5:00

CLASSROOM: Medical School, Room 211C

COURSE FACULTY: Bill Sanns

OFFICE LOCATION and HOURS: By appointment only

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READ THIS DOCUMENT CAREFULLY - YOU ARE RESPONSIBLE FOR ITS CONTENTS.

COURSE DESCRIPTION

This interdisciplinary course is designed to train participants in the necessary data management and quality control procedures required for the conduct of patient-oriented clinical research.

Pre-requisites – None

Semester credit hours – 2

By the end of this course, each student should be able to:

1. Understand the principles of data management as they pertain to clinical research
 - a. Using and Defining meta data
 - i. Develop and define data collection instruments, questions, values, computerized validation checks
 - b. Research logistics
 - i. Understanding just how to get started, perform a gap analysis, basic project activity and timeline management, reviewing costs and finances, understanding study support staff, collaborators, managing source data and data sharing
 - c. Data Security
 - i. Describe and carry out specific, practical strategies for safeguarding data quality and security, including best practices for quality control, data backup, and information security
 - d. Randomization
 - i. Basic understanding on why randomization is done, randomization techniques, and randomization implementation
2. Understand supporting principles
 - a. Data management and Analysis ethics
 - i. Data Management: Understanding the difference between ethics, law, and morals, understanding the different functional activities in a clinical research environment and how they differentiate and employ those three.

- ii. Analysis: Knowing the importance of data and analysis code control and configuration management to produce repeatable results.
 - b. Compliance
 - i. Understanding the importance of data collection and source data management, how Good Clinical Practice (GCP) and data integrity affect quality research, overview of research regulatory requirements, and how to prepare for an audit.
 - c. Quality Control
 - i. Understanding how research protocols are reviewed prior to opening, why we do active accrual monitoring, how to prepare for a quality control audit, under what federal guidance audits and research fall, and the three Rs (Recognize, Record, Report)
 - d. Program Evaluation
 - i. Gain an understanding on the different evaluation programs, a review of common tools and roles, the evaluation cycle, and the general components of evaluation methods.
- 3. Using the REDCap Electronic Data Capture (EDC) tool
 - a. Design and build a data collection instrument
 - b. Design and build a survey
 - c. Design and build a longitudinal study
 - d. Build a report
 - e. Import external data from Excel
 - f. Export data to Excel
- 4. Using Excel
 - a. Open and manage a Comma Separated Value (csv) file
 - b. Create a pivot table to analyze REDCap data
 - c. Create a chart
 - d. Link source data to Excel spreadsheets
- 5. Using PowerPoint
 - a. Link Excel charts and data directly in a PowerPoint presentation
- 6. Be able to identify individuals and resources within the institution that can provide guidance in all areas covered.

COURSE ORGANIZATION

Materials –

Computer: Students will need to have a laptop and connect to the HSCWave wireless network. Contact University Desktop Support (210.567.7777) if you need any assistance. NOTE: It may be possible to manage with a large mobile device (e.g., iPad, tablet, etc.,) as long as you are capable to run the software needed. If don't have access to a laptop, please contact the course director to make arrangements.

Books:

Software: Students will need to have an internet browser, and Microsoft Office 2010 or higher. We will be using a web-based data management system, Excel, and PowerPoint.

Reading Assignments – None prior to start of class

ATTENDANCE

Attendance at scheduled classes and examinations is crucial to meeting course objectives. Therefore, regular attendance in class is expected of each student.

- Attendance is defined as being present within 15 minutes after the scheduled beginning of the class and until 15 minutes before the scheduled ending of the class.
- Excused absences may be granted by the Course Director in cases such as formal presentations at scientific meetings, illness, or personal emergency.
- Excused absences are considered on an individual basis and require electronic communication with the Course Director to request an excused absence. The e-mail request to the Course Director for consideration of an excused absence must provide details regarding the circumstances and specific dates.
- It is expected that students will provide *advanced notice* of absence for scheduled events.
- If a student has excessive unexcused absences in a given course, they will automatically receive a grade of *unsatisfactory* unless *makeup* has been approved by the Course Director.
- Makeup of absences (both excused and unexcused) is allowed at the discretion of the Course Director.
- Allowable unexcused absences will be determined by the credit hours of the course as follows:

Course Semester Credit Hours	Allowable Unexcused Absences
3.0	3
2.0	2
1.0	1

Should you have any questions regarding attendance requirements for any course, please contact the course director.

The above policies have been put in place to ensure that all students taking MSCI courses are able to meet the intended course objectives. Repeated absences make it impossible to achieve course objectives and there are times when a make-up assignment may not provide the full knowledge the student would have achieved while in class. Your success is important to the course directors and directors of the MSCI Program.

TEXTBOOKS

Required: All materials will either be original, public domain, or open source. No books are required.

Recommended: Will be provided with the appropriate lectures

GRADING POLICIES AND EXAMINATION PROCEDURES

MEDI 5074 is a “hands on” class with projects and assignments due nearly every week. There will also be one final project due at the end of the semester. Any exams will be used by the instructor to gauge and evaluate comprehension rather than grade the student. As a result, course assignments and projects will constitute all grading possibilities.

If a student fails to turn in TWO semester projects or does not complete the final project, the resultant grade will be “Fail”.

Grading System

MEDI 5074 is a Pass/Fail course

REQUESTS FOR ACCOMODATIONS FOR DISABILITIES

In accordance with policy 4.2.3, **Request for Accommodation Under the ADA and the ADA Amendments Act of 2008 (ADAAA)**, any student requesting accommodation must submit the appropriate request for accommodation under the American with Disabilities Act (ADA, form 100). To his/her appropriate Associate Dean of their School and a copy to the ADA Coordinator. Additional information may be obtained at <http://uthscsa.edu/eeo/request.asp>.

ACADEMIC INTEGRITY AND PROFESSIONALISM

Any student who commits an act of academic dishonesty is subject to discipline as prescribed by the UT System Rules and Regulations of the Board of Regents. Academic dishonesty includes, but is not limited to, cheating, plagiarism, collusion, the submission for credit of any work or materials that are attributable in whole or in part to another person, taking an exam for another person, signing attendance sheets for another student, and any act designed to give unfair advantage to a student or the attempt to commit such an act. Additional information may be obtained at <http://catalog.uthscsa.edu/generalinformation/generalacademicpolicies/academicdishonestypolicy/>

TITLE IX AT UTHSCSA

Title IX Defined:

Title of the Education Amendments of 1972 is a federal law that prohibits sex discrimination in education. It reads “no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.”

University of Texas Health Science Center San Antonio’s Commitment:

University of Texas Health Science Center San Antonio (UTHSCSA) is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UTHSCSA does not discriminate on the basis of sex in its education programs and activities, and it encourages any student, faculty, or staff member who thinks that he or she has been subjected to sex discrimination, sexual harassment (including sexual violence) or sexual misconduct to immediately report the incident to the Title IX Director.

In an emergency, victims of sexual abuse should call 911. For non-emergencies, they may contact UPD at 210-567-2800. Additional information may be obtained at <http://students.uthscsa.edu/titleix/>

EMAIL POLICY

All correspondence will be sent to the student using the student’s LiveMail address and CANVAS. All correspondence from the student to the course director should be sent to the course director’s e-mail as listed on the first page of this syllabus.

USE OF RECORDING DEVICES

Only with course director’s or instructor’s permission.

ELECTRONIC DEVICES

TSCI 5074
Spring 2018

Cell phones must be turned off during all class meetings and exams. Computers and electronic tablets are allowed only for participating in classroom activities (*e.g.*, viewing slides presented in lecture or conference materials). No texting, tweeting, e-mailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is permitted.

TENTATIVE CLASS SCHEDULE

This class schedule is presented in the manner of one class per week. If the entire class would like to opt to an alternate schedule, we may do so; however, it must be the ENTIRE class that agrees. Many students have had to get supervisor or Chair permission to attend this class, and we cannot do anything that may interfere with that permission or their instructions. If we do move to an alternate schedule, we CANNOT start before the semester begins and we MUST finish before the semester ends. An alternate schedule is offered so that we may simulate “real world” events and activities where a fluid or changing schedule is very common.

Common changes include, but are not limited to:

1. Double lectures to either skip specific weeks or finish the semester early
2. Making some weeks all lecture and others all practical
3. Moving specific lectures to “on line” via Canvas
4. Combinations of the above

IMPORTANT and to reiterate: The entire class must agree to ANY change to the weekly meeting on this syllabus. NOTE: The topics and dates listed may be changed to accommodate any potential external speakers for the “Special Topics in Data Management” lectures. The students help to select the “special topics” and we have to be as flexible as possible to bring in the appropriate subject matter experts.

Class	Tentative Date	Topic
1	1/9/2018	Welcome and Introduction Syllabus Review Data Management Defined Creating your REDCap accounts
2	1/16/2018	Ethics in Data Management REDCap Basics
3	1/23/2018	Data Collection Instruments
4	1/30/2018	Study Design
5	2/6/2018	Security
6	2/13/2018	Meta Data Reporting
7	2/20/2018	Longitudinal Studies
8	2/27/2018	Randomization
9	3/6/2018	Standard Operating Procedures Final project definition and discussion

10	3/13/2018	Spring Break
11	3/20/2018	Research Data Management Logistics
12	3/27/2018	Program Evaluation
13	4/3/2018	Quality Systems, Effectiveness, Efficiency
14	4/10/2018	How to work with consultants Statements of Work Project Consulting for final project
15	4/17/2018	Compliance Auditing
16	4/24/2018	Special Topics in Data Management: TBD
17	5/1/2018	Special Topics in Data Management: TBD Turn in final projects

Class: 1
Tentative Date: January 9, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Data Management
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none"> • Define data management • Describe the differences between data collection and data management
Class Assignment: <ul style="list-style-type: none"> • Students will create REDCap data accounts • Students will watch an introductory REDCap videos <ul style="list-style-type: none"> ○ https://projectredcap.org/resources/videos/
Readings: Handouts at time of class

Class: 2
Tentative Date: January 16, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Ethics in Data Management
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none"> • Develop an understanding of ethics in the data management process • Describe the differences between Ethics, Morals, and Law

Class Assignment:

1. REDCap Hands On
 - a. Create a new REDCap project
 - b. Develop a REDCap data collection instrument
 - c. Review instrument question types

Readings: Handouts at time of class

Class: 3

Tentative Date: January 23, 2018 (3:00 - 5:00 pm)

Room: Medical School, 211C

Instructor(s): Bill Sanns

Topic: Data Collection Instruments

Learning Objectives and Competencies– Participants will be able to:

- Create a well-structured and validated data collection instrument utilizing
 - Well formulated questions
 - Appropriate field and variable types
 - Verbose and unique variable names

Class Assignment:

- REDCap Hands On
 - Review and assess the previous week's assignment using this current week's techniques
- Instructions for the following week's lecture

Readings: Handouts at time of class

Class: 4

Tentative Date: January 30, 2018 (3:00 - 5:00 pm)

Room: Medical School, 211C

Instructor(s): Bill Sanns

Topic: Study Design

Learning Objectives and Competencies– Participants will be able to:

- Develop a mock research study to utilize for future assignments
- Create a series of measurable research questions

Class Assignment:

- REDCap Hands On
 - Review and assess the previous week's assignment using this current week's techniques

Readings: Handouts at time of class

Class: 5

Tentative Date: February 6, 2018 (3:00 - 5:00 pm)

Room: Medical School, 211C

Instructor(s): Bill Sanns

Topic: Security

Learning Objectives and Competencies– Participants will be able to:

- Define a list of data management specific pragmatic security measures

Class Assignment:

- REDCap Hands On
 - Question Matrix
 - Asking a lot of related data in a concise and easy to manage mechanism
 - Branching Logic
 - If “abc,” Then “123”
 - Scripting
 - Customizing functionality with YOUR code

Readings: Handouts at time of class

Class: 6

Tentative Date: February 13, 2018 (3:00 - 5:00 pm)

Room: Medical School, 211C

Instructor(s): Bill Sanns

Topic: Study meta-data and basic reporting

Learning Objectives and Competencies– Participants will be able to:

- Describe the data and parameters that defines their data management requirements
- Build a series of data driven reports

Class Assignment:

Excel reporting basics

- Creating and saving a worksheet
- Formatting data
- Entering in a formula

REDCap class exercises:

- Using the data dictionary to create an instrument
- Data import
- Simple data export

Excel class exercises:

- Pivot Tables: creating table summaries
 - Graphs: visual data display

Readings: Handouts at time of class

Class: 7

Tentative Date: February 20, 2018 (3:00 - 5:00 pm)

Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Longitudinal Studies
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Describe the data management needs for studies conducted over time and multiple visits
Class Assignment: REDCap class exercises: <ul style="list-style-type: none">• Working with the data dictionary• Creating events• Scheduling subjects
Readings: Handouts at time of class

Class: 8
Tentative Date: February 27, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Randomization
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Define several randomization methods• Build randomization schedules
Class Assignment: REDCap class exercises: <ul style="list-style-type: none">• Setting up a REDCap randomization schema• Creating reports• Exporting data
Readings: Handouts at time of class

Class: 9
Tentative Date: March 6, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Standard Operating Procedures
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Define the needed Standard Operating Procedures required for a research project• Create a Standard Operating Procedure
Class Assignment: <ul style="list-style-type: none">• Final project discussion, requirements definitions, and expected parameters
Readings: Handouts at time of class

Class: 10
Tentative Date: March 13, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Spring Break
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Take a week off from attending class
Class Assignment: <ul style="list-style-type: none">• Be safe
Readings: N/A

Class: 11
Tentative Date: March 20, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Research Data Management Logistics
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Perform a “gap” analysis• Define your “project triangle”• Understand how project scope affects time and cost• Define the differences between grants and contracts
Class Assignment: <ul style="list-style-type: none">• Excel and Powerpoint Data Linking
Readings: Handouts at time of class

Class: 12
Tentative Date: March 27, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Program Evaluation
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Define program evaluation• Determine what constitutes a successful project
Class Assignment: <ul style="list-style-type: none">• Define an evaluation plan for the course test project
Readings: Handouts at time of class

Class: 13
Tentative Date: April 3, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Quality Systems, Effectiveness, Efficiency
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Define the requirements for a “quality system”• Describe the difference between Efficiency and Effectiveness in a research data management environment
Class Assignment: <ul style="list-style-type: none">• Open discussion related to these topics in our everyday working environment
Readings: Handouts at time of class

Class: 14
Tentative Date: April 10, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Working with Consultants, Creating Statements of Work
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Define and create a statement of work
Class Assignment: <ul style="list-style-type: none">• Work with consultants (provided by instructor) related to final project• Develop a statement of work for your final project.
Readings: Handouts at time of class

Class: 15
Tentative Date: April 17, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Compliance and Auditing
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Explain the difference between compliance and auditing• Describe and define the processes to prepare for an audit• Define the products, deliverables, and conditions necessary to meet audit requirements
Class Assignment: <ul style="list-style-type: none">• Finalize all “final project” requirements and expectations
Readings: Handouts at time of class

Class: 16
Tentative Date: April 24, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Special Topics in Data Management. NOTE: The instructor will most likely change during this week depending on the topic chosen by the class, the availability of instructors, etc. Also, give the issues with availability, this topic may be taken out of sequence to accommodate a guest lecturer's schedule.
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Objectives based on topic
Class Assignment: <ul style="list-style-type: none">• Based on topic
Readings: Handouts at time of class

Class: 17
Tentative Date: May 1, 2018 (3:00 - 5:00 pm)
Room: Medical School, 211C
Instructor(s): Bill Sanns
Topic: Final Project Presentations
Learning Objectives and Competencies– Participants will be able to: <ul style="list-style-type: none">• Present their research project(s)
Class Assignment: <ul style="list-style-type: none">• Final project will be defined during the course of the semester with input from students. The presentation medium will be dependent on the project mechanism
Readings: N/A