TSCI 5074
Spring 2023

TSCI 5074: Data Management, Quality Control and Regulatory Issues

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

CLASSROOM: ALTC 2.219 (Subject to change)

COURSE FACULTY: Susanne Schmidt, PhD

OFFICE LOCATION and HOURS: By appointment only through MS Teams

EMAIL: schmidts4@uthscsa.edu

TELEPHONE: 210 567 0905 (office)

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)
   
   ii. Gain understanding of continuous quality improvement tools (e.g. Lean Six Sigma, Rose Bud Thorn)

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.
   
   ii. Gain insights into communicating with stakeholders.

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. 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 or computer and connect to the HSCWave wireless network or other internet to attend class and complete assignments. 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*: none

*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 (REDCap), Excel, and PowerPoint.

**Reading Assignments**

None prior to start of class.

All class materials will be available on CANVAS.

**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:

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<thead>
<tr>
<th>Course Semester Credit Hours</th>
<th>Allowable Unexcused Absences</th>
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<tbody>
<tr>
<td>3.0</td>
<td>3</td>
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<tr>
<td>2.0</td>
<td>2</td>
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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

TSCI 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

TSCI 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
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.