



**The University of Texas at El Paso
College of Health Sciences
Clinical Laboratory Science Program**

Course Title: Clinical Investigation
Course Number: CLSC 4274
Course Hours: Friday from 1:00-3:00 pm
Course Location: CHS 135
Credit Hours: 3
Course Coordinator: Gabriel Ibarra-Mejia, M.D., Ph.D., MScErg
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Office email: gabmejia@utep.edu
Office hours: Mondays 10:00am-12:00pm & 2:00-4:00pm.

Recommended Course Textbook: Introduction to Health Research Methods: A Practical Guide; Kathryn Jacobsen, 2nd ed, © 2017



COURSE INTRODUCTION

Course Description

The clinical investigation course CLSC 3274 will cover research in medical/clinical settings with a focus on research planning, design, data collection and dissemination, and evaluation of published studies. Students will design and perform research to include proposal writing. Correlation of disease states and changes in laboratory values will also be included as case studies.

Course Goal

The Clinical Laboratory Scientist serves in a research role in numerous instances in the clinical laboratory. In accordance with the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), Standard 22 B, the student will acquire knowledge of research design/practice sufficient to evaluate published studies as an informed consumer.

Healthy People 2020

This course is in alignment to the Healthy People 2020 Task force (www.healthypeople.gov) initiative. Clinical laboratory scientists are critical in achieving its mission to:

1. Identify nationwide health improvement priorities.
2. Increase public awareness and understanding of the determinants of health, disease, and disability and the opportunities for progress.
3. Provide measurable objectives and goals that are applicable at the national, State, and local levels.
4. Engage multiple sectors to take actions to strengthen policies and improve practices that are driven by the best available evidence and knowledge.
5. Identify critical research, evaluation, and data collection needs.

The goals of this task force are to:

1. Attain high-quality, longer lives free of preventable disease, disability, injury, and premature death.
2. Achieve health equity, eliminate disparities, and improve the health of all groups.
3. Create social and physical environments that promote good health for all.
4. Promote quality of life, healthy development, and healthy behaviors across all life stages.

Types of Instruction:

Learning methods involved in this course include independent reading assignments, lectures, small group activities, homework, a research project, exams/quizzes and an oral presentation.

Course Goals:

To successfully complete the Clinical Investigation course, the student will:

1. Demonstrate a basic understanding of the scientific method and use it to design and test a hypothesis, analyze data and present the project to colleagues in an academic format.
2. Demonstrate an understanding of the regulatory processes in place for human protections in scientific research and be able to submit a human scientific study protocol for approval.
3. Understand the history and importance of scientific ethics in human subjects research.
4. Demonstrate a functional understanding of statistical methods for data evaluation.
5. Demonstrate the ability to locate, critically read and fundamentally understand and interpret scientific literature.
6. Demonstrate the ability to design, execute and troubleshoot a scientific protocol.
7. Demonstrate and employ effective interpersonal, professional and group communication skills.
8. Demonstrate the ability to actively discuss and debate scientific questions.
9. Understand the implication of quality control and quality assurance in the pre-analytical, analytical and post-analytical collection of clinical samples for clinical research.

Objectives

Affective Domain

Upon completion of the course, the student will be able to exhibit the appropriate responsible behaviors by demonstrating:

1. A positive attitude by being prepared for lecture and laboratory sessions completing assigned tasks on time and displaying self-motivation.
2. Organization by utilizing time effectively, sequencing and prioritizing tasks for completion with time constraints and maintaining a neat clean work.
3. Attention to detail by diligently pursuing accuracy and documenting data accurately and legibly.
4. Problem solving ability by identifying a scientific question, perform scientific techniques, interpret technical data, recognizing discrepancies in techniques or procedures and presenting the data to peers.
5. Dependability by following directions, working independently after being given directions.
6. Stability and self-confidence by approaching and performing routine tasks confidently without assistance and maintaining composure.
7. Appropriate interpersonal skills by cooperating and communicating effectively with classmates and instructors and displaying courteous, considerate behavior and appropriate appearance.

8. Ethical behavior and integrity by respecting confidentiality of patient information, complying with professional standards and code of ethics, adhering to safety policies and abiding by all rules and regulations of the institution.

Psychomotor Domain (evaluated in CLSC 3155)

Upon completion of the course, the student will be able to display sufficient coordination and manual dexterity to understand a scientific protocol, perform the technical aspects of experiments and evaluate the significance of the data. These functions include, but are not limited to the following:

1. Design experiments and perform technical procedures.
2. Determine the statistical methods necessary for data analysis.
3. Interpret technical data results.
4. Document the performance of procedures and data collection.
5. Evaluate data in a critical manner and draw conclusions about its clinical significance.

Cognitive Domain Objectives

Upon completion of the course, the student should be able to:

Introduction to Clinical Investigation

1. Define what is meant by method.
2. Outline some common methods of scientific enquiry.
3. Outline the scientific method
4. Compare qualitative and quantitative approaches to research
5. Discuss how the scientific method is applied to conducting health science research
6. Define authority, rationalism and intuition
7. Define skepticism, determinism and empiricism
8. Understand the difference between a hypothesis and a theory
9. Understand the concept of deductive reasoning
10. Understand and define the differences between observational and experimental study designs
11. Understand the differences between retrospective and prospective studies
12. Understand how to critically break down, read and understand a scientific journal article
13. Define the 4 stages involved in a clinical trial study

Human subject protections, regulatory boards and research ethics

1. Understand the history leading to the establishment of guidelines for conducting human subjects research
2. Understand the role of the Institutional Review Board (IRB) in the approval and regulation of human studies
3. Understand what is meant by "protected groups"
4. Understand and explain the procedure and purpose for giving informed consent for children, adults and protected groups
5. Explain the principles of justice, beneficence and respect for persons in human subjects research
6. Define the principles of exempt, expedited and full-board reviews of human subjects studies
7. Explain what constitutes human subject privacy and confidentiality
8. Define the 18 key identifiers of patient identity in human subjects research
9. Understand what constitutes ethical behavior in clinical research

10. Understand how privacy, minimization of subject discomfort and coercion impact human subjects research

Design and Performance of Human Subjects Research

1. Discuss how research questions are selected and justified
2. Specify how questions are transformed into empirically testable hypotheses or aims
3. Broadly outline research strategies available for specific types of investigations
4. Discuss the ethical and economic constraints on the planning and execution of research
5. Understand the difference between and be able to define experimental, quasi-experimental, single case research, survey and qualitative research studies
6. Define what is meant by sampling and representative samples
7. Outline the relative advantages and disadvantages of commonly used sampling methods.
8. Discuss the relationship between sampling error and sample size
9. Examine the concept of external validity for generalizing research finding to other settings.
10. Understand the process for individual and population sample selection within a study
11. Explain the difference between random, incidental and systemic study sampling
12. Understand the implication of quality control and quality assurance in the pre-analytical, analytical and post-analytical collection of clinical samples for clinical research

Data Evaluation and Reporting

1. Identify the strengths and weaknesses of research publications
2. Identify, describe and understand the key components of a research article
3. Discuss the implications of identifying problems in design, measurement and analysis in a given publication
4. Outline strategies for summarizing and analyzing evidence from a set of papers
5. Discuss the implications of critical evaluation of research from health care practices
6. Understand and utilize appropriate statistical modalities to analyze and interpret experimentally-obtained data.
7. Outline and discuss conclusions drawn from experimental data and statistical analyses
8. Describe the features of a successful scientific lecture and poster presentation
9. Construct a poster outlining each of the aspects pertaining to the classroom research project and present the poster to classmates and professional colleagues

GENERAL COURSE POLICIES:

Academic dishonesty. Academic dishonesty of any type **WILL NOT** be tolerated. Students found guilty of academic dishonesty will be subject to disciplinary action including but not limited to the possibility of a failing exam grade, failure of the course and possible dismissal from the University.

Regent's Rules and Regulations, Part One, Chapter VI, Section 3, Subsection 3.2, Subdivision 3.22. "Scholastic dishonesty includes but is not limited to cheating, plagiarism, collusion, submission for credit of any work or materials that are attributable in whole or in part to another person ***(including copying homework or other material from another individual)***, taking an examination for another person, any act to give unfair advantage to student or the attempt to commit such acts."

Section V, Sub-section K of the CLS student handbook states:

1. Absolute honesty and integrity are a critical aspect of your chosen profession. Confidentiality of patient information is another. These must be strictly observed.

2. Any student who falsifies patient records and/or results, cheats on quality control results, interferes with laboratory functions, deliberately cheats on any CLS program exam or exhibits any of the behaviors listed in the Probation/Dismissal policy will be considered to be in violation of both the UTEP and CLS program policies, and may be subject to immediate dismissal from the clinical practicum and the CLS program itself.

3. If such a dismissal is warranted from the CLS Program, a detailed signed statement will be permanently placed in the student's files

Cell phone and laptop policies. Usage of cell phones during class periods is not conducive to learning and is disruptive to others. Cell phones must be put away and not used during class. Individuals violating this policy will be asked to leave class and will not receive credit for that day's activities.

Laptop computers can be used for taking notes and viewing online texts *only*. Checking email, doing other work or playing games during class is expressly forbidden. Students violating this policy will lose the privilege of using a computer during the class period.

Audio and video recording. No audio and video recording will be allowed with the exception of those that meet accessibility accommodation. Any student found to be in violation of this policy will be subject to disciplinary action that may include dismissal from the course, the CLS program and from the University.

Behavioral Conduct. The student is expected to conduct themselves in a respectful and professional manner. No disrespect toward the instructor OR to other students will be tolerated. Students found to be acting contrary to this policy will be counseled, may be referred to the Program Chair, and may be subject to disciplinary action.

Students with disabilities. If you have or suspect a disability and need accommodation, you should contact The Center for Accommodations and Support Services (CASS) at 747-5148. You can also email the office at cass@utep.edu or go by the Union Building East, Room 106. For additional information, visit the CASS website at <http://sa.utep.edu/cass/>. It is the responsibility of the student to notify the instructor that CASS accommodation guidelines are needed. CASS accommodations are NOT retroactive and no accommodation will be made for students that have not received approval through CASS.

University Counseling Center. If you have personal issues and require assistance, counseling services and resources are available online and in person through the Division of Student Affairs. You can access these services online (<http://sa.utep.edu/counsel/>), by phone (747-5302) or in person.

Counseling Center
202 Union West
El Paso, Texas 79968

ACADEMIC POLICIES:

Course participation. Students are expected to actively participate in the learning process by completing assignments, activities and service learning engagements. Engagement in these activities is vital for success as well as getting the most you can out of this course.

COURSE ASSESSMENT

Course Grading:

50% Course exams (Three online section exams-10% each and a course final-20%)

30% Class research project

10% Class homework assignments

10% Service-based learning and participation in the research project activities

Grading Scale:

A 90-100%

B 80-89%

C 75-79%

D 70-74%

Failing 69% and below

Exams. Three standard semester exams will be administered online via BlackBoard. A final exam of the same format will be administered online during finals week. Exams will primarily include multiple choice and true/false questions pertaining to material discussed in class.

Group research project. Students will participate in a class-wide group research project pertaining to some aspect of Clinical Laboratory Science. This project will be one that engages the student in the active research process while also walking students through the intellectual process of scientific inquiry. Students will learn how methods behind designing, executing and presenting clinical research projects. This project will be presented to the class during the second week of the course and students will be expected to participate in collection and analysis of data for the project throughout the semester.

Homework. Students will be asked to complete homework assignments that reinforce material learned during the duration of the course. The assignments will ask the student to synthesize the information gained from the lectures and apply them to “real-world” research problems. No late homework assignments will be accepted. Homework submitted after the due date will receive a grade of zero. As part of the homework, students will be required to create a poster detailing the class project to be presented on the day of the Course Final.

Service-based learning. Each student will be asked to contribute to data collection and analysis activities as part of the course grade. Participation in service-based learning activities tied to an active research project will provide opportunities for students to develop skills in community engagement, leadership and communication.

Attendance and participation. Students are expected to attend class regularly, be prepared for the day’s work and actively participate in the learning process. Attendance and participation will be included as part of the Affective Domain assessment for the course and will be used in grade calculation. Being tardy for class can be disruptive to other students, so being on time and prepared to begin is important. In-class activities (individual and group) will be used as an objective measure of student participation.

Examples of absences are included below:

Acceptable Absences: Medical emergencies, military deployment, UTEP-approved activities

Unacceptable Absences: Vacations, doctor's appointments, personal meetings, chronic tardiness

STUDENT GRADE APPEALS AND DISMISSAL

Dismissal Policy (CLS Student Handbook, Section IX). Students will be dismissed from the Clinical Laboratory Sciences Program for unsatisfactory academic performance defined as a cumulative grade **less than 75%** in ***any*** CLS course.

Grade Appeals Process

(<http://sa.utep.edu/studentlife/#grade-grievance>)

Those students who believe that they have been evaluated unfairly have options for appeal. The due process procedure is as follows (*CLS student handbook, section XI*):

Step 1: Attempt to resolve the difficulty with the faculty member.

Step 2: If the dispute cannot be resolved in Step 1, the student may appeal to the program director within 5 school days stating the evidence for the continued dispute in writing.

Step 3: If the matter remains unresolved, a written complaint outlining the evidence and reason for the dissatisfaction of the decision must be submitted to the Assistant Dean of the College of Health Sciences. The Assistant Dean will call upon the Due Process Committee to review and make recommendations to the Assistant Dean based on statements, written evidence, and interviews with all parties involved.

Step 4: If an unsatisfactory solution has been reached, the complainant will then notify the Dean within five (5) school days, who will pursue the matter with the Vice President for Student Affairs.

TENTATIVE CLASS SCHEDULE

Lecture Week	Date	Topic
1	Aug 30	Course Introduction/Syllabus
2	Sept 6	The Health Research Process Chapter 1
3	Sept 13	Selecting a General Topic and Reviewing the Literature Chapters 2 and 3
4	Sept 20	Focusing the Research Question Chapter 4
5	Sept 27	Study Designs-Overview, Case series, cross-sectional surveys Chapters 7-9 Exam 1
6	Oct 4	Study Designs-Case-control , Cohort, and Experimental Chapters 10-12
7	Oct 11	Study designs-Qualitative and Correlational studies Chapters 13-14
8	Oct 18	Research Protocols Chapter 15
9	Oct 25	Population Sampling and Sample size estimation Chapters 16 and 17 Exam 2
10	Nov 1	Questionnaire development, surveys and interviews and Other Assessments Chapters 18-20
11	Nov 8	Secondary analyses, Systematic Reviews and Meta-Analyses Chapters 21-22
12	Nov 15	Ethical Considerations, Review and Approval Chapters 23 and 24 Exam 3
13	Nov 22	Data management and Statistics Chapters 26-30
14	Nov 29	Thanksgiving-No Class
15	Dec 6	Posters and Presentations and Articles Chapters 31-35
16	Dec 14	Final Exam (Room TBD)