Course Syllabus
DRSC 4330
Clinical Research for Rehabilitation Sciences
The University of Texas at El Paso

Course Number: DRSC 4330 (Spring 2024)
Course Title: Clinical Research for Rehabilitation Sciences
Catalog Course Description: Group and single-subject designs utilized for research in rehabilitation sciences.

Course Prerequisites: Admission to the Bachelor of Science in Rehabilitation program or department approval; PSYC 1303, DRSC 1301, DRSC 4301.

Semester Credit Hours: 3

Class Schedule: Monday (online, self-Study), Wednesday (Face to Face, Instructor Led) from 6:00pm to 7:30pm

Class Location: Medical Center of the Americas Foundation (MCA)'s Cardwell Collaborative Building - 5130 Gateway Blvd. East, El Paso, TX. 79905 (Large Conference Room, 1st Floor). Parking is available to students just outside the building.

Faculty: Carolina Valencia, PhD

Instructors: Laura Herrera, DNP, Sub-I Western Sky Medical Research
Sergio Guerrero, MD Site Engagement Manager US & Mexico, ICON/ USB Pharma
Catherine Posey, CCRC, COO, Western Sky Medical Research
Anna Yvonne Rodriguez, CEO, Owner, Egality Sciences, LLC
Allen Savedra, CRA II, ICON Strategic Solutions
Wenoah Veikley, RN, BScN, CEO, CCO, Owner, Axces Research
Jesse Young, Ph.D., Medical Director, TriCore Reference Laboratories
Deborah Clegg, PhD., VP Research, Texas Tech University Health Sciences Center

Office Location: Students are encouraged to reach out to the instructors during the week with questions as needed.

Office Hours: When unforeseen circumstances and conflicts arise during this time, electronic office hours will be held at another time.

Required Readings: Additional readings will be provided to students electronically or in hard copy. Weekly articles, infographics, case reports and web-based presentations will be assigned. Students are required to read these and be prepared to discuss them during class. Students are expected to research and find resources required for assignments.

Textbook:
Course material will be available through ACRP's Learning portal.

Gast, D. L. (2010). *Single subject research methodology in behavioral sciences*. New York, NY: Routledge.

Garrard, J (2014) Health sciences literature review made easy: The matrix method, 4th ed. Jones & Bartlett Learning, Burlington, MA.

Kratochwill, T. R., & Levin, J. R. (Eds.). (2014). *Single-case intervention research: Methodological and statistical advances*. Washington DC: American Psychological Association.

Format: The course is an interactive format where faculty will provide a structure and format for class sessions and students are expected to come prepared, make an active, significant contribution to the discussions. Students have the responsibility for demonstrating their knowledge of assigned readings, which are expected to be completed PRIOR to the session assigned. The course also includes instructor presentations and in-class activities. Each student will be assigned a date where they will be asked to share something about themselves and what they learned from the assigned course topic for that week at the beginning of each class. In addition, we will ask students to respond to periodic surveys on a bi-annual basis for a minimum of a 4-year period. Sample questions will include, for example, the student's career title/ occupation, salary range, and geographic location. Information obtained would be aggregated and utilized for reporting purposes ONLY to track the success of the program.

Blackboard and eLearning portal: The electronic platform for this course will be Blackboard (grading platform). Students are responsible for checking Blackboard daily for course announcements and updates through the my.utep.edu portal. Course material will be available through 1) ACRP's Learning portal. Students enrolled in the class can access the ACRP eLearning platform via the following link http://learning.acrpnet.org.
Students will receive this link and login instructions via an email from —ACRP. If you already have an ACRP account, you are aligned to The Medical Center of the Americas Foundation in ACRP's system and are ready to go. If you **do not** yet have an ACRP account, please follow these steps:

1. Visit http://acrpnet.org/newuser
2. Enter your The Medical Center of the Americas Foundation email address and click the 'Search' button.
3. When The Medical Center of the Americas Foundation appears, click the 'Register with this Organization' button.
4. Complete the account creation process by entering your demographic information.
5. After your account is created, you will be automatically directed to your personal profile.
6. Once you're on your new account profile, click the 'My Learning' button and you will be directed to the ACRP learning environment, where you can access your courses by clicking the "Go to My Courses Dashboard" button.

Course Goals:

1. Teach entry level CRC competencies that focus on the ability to perform basic tasks and exhibit the knowledge and key aspects of clinical research at an essential or foundational level. For the most part it is presumed that the entry level CRC will evolve in their ability to move from a basic level of understanding to the ability to perform a variety of tasks under direct supervision.
2. It is anticipated that the entry level CRC will gradually be exposed to and have the opportunity to demonstrate their competencies across several different types of clinical studies (investigational products, study phases, therapeutic areas and indications).
3. Key behavioral competency descriptors include: define, describe, list, and explain.

Learner Objectives: By completing the class, the learner will be able to:

1. Encompass knowledge of scientific concepts related to the design and analysis of clinical trials. For example, identify key protocol elements and related study task, describe the types of common study designs including basic understanding of scientific research (method, statistics, and results), explain the purposed of the Investigator Brochure, plan/report and the key elements contained within these documents, etc.
2. Explain basic elements of subject safety including reasoning behind required use of an Investigational Review Board (IRB), Independent Ethics Committee, study activity documentation, and event reporting requirements.
3. Explain the investigational products development process and identify key regulations to control these processes.
4. Explain how to perform study operational activities in compliance with Good Clinical Practice (GCP)
5. Understand and explain how to perform study non-GCP related study management activities such as steps for participating in a clinical study, the purpose and elements of a study plan, elements of a study budget, various types of third-party vendors that may be needed to conduct a clinical study, workflow processes between the site and vendor(s), etc. Understand and explain how to document the data according to ALCOA-C (Attributable, Legible, Contemporaneous, Original, Accurate and Complete) principles. Understand and explain the importance of professional conduct and describe leadership principles hat impact the effective operation of an investigative site such as roles and contribution of individuals serving in leadership, management and mentor capabilities, ethical and professional conflicts, etc.
6. Understand and explain the variety of communication channels, roles, an relationship outlets for study results that impact the conduct of clinical research such as the relationship between the Sponsor, CRO, and clinical research site personnel, trial participants, and their family members, the subject's Primary Care Physician (PCPs) or treating physicians including the basics of appropriate communication chains of command. Identify where the clinical study results may be published (e.g. clinicalstudies.gov, scientific publications) and locate such results.

Class Participation and Attendance: Active participation in this course is very important and is encouraged. Students should be prepared to come to class to discuss, answer questions, and participate in all class activities. Students are expected to ask questions, participate in group dialogue and throughout the course particularly via the instructor-led sessions. Attendance will be recorded during each instructor-led session. Students can miss one (1) instructor-facilitated session and those logged in virtually must check in/out via zoom at the beginning and end of each session. Any additional absences must be approved on a case-by-case basis by the program director - michaele@mcamericas.org, for the student to receive their certificate of completion for this course.

Total Grade Points: The maximum number of points that can be earned in this class is 100. The translation of points to a letter grade for this course is as follows:

A (> 90 %),
B (80-89%),
C (70-79%),
D (60-69%),
F (< 60%).

Letter grades based on this distribution will then be assigned to each student.

Students must complete 15 modules and 2 Clinical Research Knowledge Assessments during 11 sessions. Each session must be completed by Saturday (of each session) at 11:59pm.

Course grades will be calculated using the following weights:

Activity	Description	% of Grade
Clinical Research Knowledge Assessment (CRKA)	Pre-course assessment to determine baseline clinical research knowledge.	**0%**
Completion of Session 1	Completion of eLearning modules # 1 and 2.	**8%**
Completion of Session 2	Completion of eLearning module # 3.	**8%**
Completion of Session 3	Completion of eLearning module # 4.	**8%**
Completion of Session 4	Completion of eLearning module # 5.	**8%**
Completion of Session 5	Completion of eLearning module # 6.	**8%**
Completion of Session 6	Completion of eLearning modules # 7 and 8.	**8%**
Completion of Session 7	Completion of eLearning modules # 9 and 10.	**8%**
Completion of Session 8	Completion of eLearning module # 11.	**8%**
Completion of Session 9	Completion of eLearning module # 12.	**8%**
Completion of Session 10	Completion of eLearning module # 13.	**8%**
Completion of Session 11	Completion of eLearning modules #14 and 15.	**8%**
Final Exam Clinical Research Knowledge Assessment (ACRP CRKA)	Final assessment to determine knowledge of course materials.	**12%**

Assignments: The following assignments will be required as part of this course:

Students must take a pre-course Clinical Research Knowledge Assessment (CRKA), pass 15 eLearning module exams, and finally pass a final Clinical Research Knowledge Assessment (ACRP CRKA) exam at the end of the course. In other words, included in the course syllabus are a pre-course exam, 15 ACRP eLearning modules, and a final course exam. Students will need to pass 15 exams via ACRP's eLearning portal which will automatically appear during and at the end of each ACRP eLearning module. Likewise, at the very end of the course students will be expected to take and pass a final Clinical Research Knowledge Assessment (ACRP CRKA) exam. Students will have two (2) chances to pass each module and final course exams. If they fail their second attempt, they will need permission from the Program Director michaele@mcamericas.org to access these materials for more learning or exam time. Please contact Rick Grendell, Senior Clinical Trial Outreach Coordinator from the Medical Center of The Americas Foundation rick@mcamericas.org if you have any question. All eLearning module exams are pass/fail.

Course Outline – IL = Instructor Led, SS = Self-Study

Session *(Date/ Time/ Instructor)*	Module	Session Title	eLearning/ Exam(s)	Pre-reads/Self-Study Resources for Participants	Infographics	Case Studies
Week 1: **Date:** Mon. January 22nd - SS Wed. January 24th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	1	**CRC Core Competency Foundations Overview and Roadmap**	Exam: *Please take the entry-level knowledge assessment for this course.*	• ACRP CRC Core Competency Foundations Training Plan • CRC competency development and assessment roadmap Final April 2020	• Entry Level CRC Competencies Mapped to PI Responsibilities	No
	2	**Clinical Research 101 Orientation**	• Intro to Clinical Trials • The Drug Development Process: Improving Trial Feasibility and Exploring Your Growth Potential	• COPD Case Study Materials • ICH E8	• Clinical Research Relationships and Documents	No
Week 2: **Date:** Mon. January 29th - SS Wed. January 31st -IL **Time:** 6-7:30 PM **Instructor:** *TBD*	3	**Clinical Research Relationships, Responsibilities Documents and Processes – Part 1 – PI Responsibilities**	• Investigator Responsibilities eLearning Module • Form FDA 1572: Getting it Right the First Time eLearning Module	• Delegation of Duties Log-TransCelerate • Documenting Oversight • FDA Guidance - Frequently Asked Questions - Form FDA 1572 • FDA Guidance - Investigator Responsibilities • Sample Oversight Plan	• PI Oversight	No

Week 3: **Date:** Mon. February 5th - SS Wed. February 7th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	4	**Clinical Research Relationships, Responsibilities Documents and Processes – Part 2 – Essential Documents**			• Essential Document Management	Yes
Week 4: **Date:** Mon. February 12th - SS Wed. February 14th - IL **Time:** 6-7:30 PM **Instructor** *TBD*	5	**Clinical Research Relationships, Responsibilities Documents and Processes – Part 3 – IRB/IEC Reports**		• FDA Guidance – IRB Continuing Review • FDA Guidance – Using a Centralized IRB Review Process	• IRB-IEC Records and Reports	No
Week 5: **Date:** Mon. February 19th - SS Wed. February 21st - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	6	**GCP / HSP Check In - Your Questions Answered!**	• Ethics and Human Subject Protection: A Comprehensive Introduction eLearning Module • Good Clinical Practice • Informed Consent Simulation Training (eLearning)	• FDA Guidance - Data Retention When Subjects Withdraw Consent • FDA Guidance - Guide to Informed Consent • FDA Guidance - Q and A Informed Consent Elements • FDA Guidance - Screening Tests Prior to Enrollment • FDA Guidance - Use of Electronic Informed Consent • WMA Declaration-of-Helsinki	• Informed Consent	No

Week 6: **Date:** Mon. February 26th - SS Wed. February 28th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	7	**Everything you need to know about ALCOA-C!**		• FDA guidance - Use of Electronic Health Record Data • FDA Guidance - Use-of-Electronic-Health-Record-Data-in-Clinical-Investigations	• Proper Data Collection	Yes
	8	**Patient Recruitment / Retention 101**	• Improving Recruitment, Accrual, Retention in Clinical Trials eLearning Module • Metrics to Improve Subject Recruitment and Retention		• Enrollment Validation • Subject Recruitment and Retention	Yes
Week 7: **Date:** Mon. March 4th - SS Wed. March 6th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	9	**Subject Safety Management Check-in!**		• FDA Guidance - AE Reporting • ICH e2a Clinical Safety Data Management	• Safety Management	Yes
	10	**IP Management and Accountability 101**	• Mastering the Event Reporting Cycle: Understanding Your Impact on Patient Safety eLearning Module	• Sample IP Management SOP • Sample IP Storage Temperature Log	• IP Management	Yes

Week 8: **Date:** Mon. March 18th - SS Wed. March 20th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	11	**Protocol / GCP Compliance and Monitoring Overview and CAPAs and Root Cause Analysis (RCA) 101**	• Key Skills for Ensuring Quality Control through Risk-Based Decision Making eLearning Module • Building Quality Management Systems for Sites and Sponsors: Root Cause and CAPA eLearning Module	• Agarwal Unanticipated Event Form • FDA Guidance - A Risk-Based Approach to Monitoring • FDA Guidance - Q9 Quality Risk Management • QCRC Protocol Deviation Log • Sample CAPA Form • Sample Monitoring Visit Report and Follow-up Letter • TransCelerate Protocol Deviation Process Guide	• Protocol and GCP Compliance • Monitoring Approaches to Decrease Risk and Increase Quality	No
Week 9: **Date:** Mon. March 25th - SS Wed. March 27th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	12	**Optimizing Study Communications - Best Practices**	• eResearch: Managing Clinical Trials in an Electronic Environment eLearning Module			No
Week 10: **Date:** Mon. April 1st - SS Wed. April 3rd - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	13	**Study Feasibility and Site Selection**	• Trial Feasibility and Selection: Their Impact on Accrual • Understanding Clinical Trial Protocols: Key Considerations for Effective Development and Feasibility Review	• Sample Feasibility Assessment Checklist • TransCelerate Site Profile Form	• Site Qualifications	No

Week 11: **Date:** Mon. April 8th - SS Wed. April 10th - IL **Time:** 6-7:30 PM **Instructor:** *TBD*	14	**Pulling it all Together: A Day in the Life of a CRC**	Exam: *Please take the entry-level knowledge assessment for this course.*			No
	15	**Core Competency Training Reflections and Wrap-Up**				No
GRADUATION **Date:** **Wed. April 17th** **Time:** 5:30-7:00 PM **Instructor:** **N/A**	Celebration Mixer & Graduation Save-the-Date					

CRC Core Competency Foundations Training Schedule:

Course Outline – IL = Instructor Led, SS = Self-Study

Class Policies

Attendance Policy: It is university policy that all students attend ALL scheduled classes and the final class session. Attendance will be taken at each class. Students are advised that pets, family, work and early vacation plans are not excuses for continual lateness, absences or missed exams and assignments. When a student registers for a course, it is assumed that she/he has made arrangements to avoid such conflicts.

Policy on Electronic Devices in Class: The necessity of classroom discussion and other interaction in this course negates the usefulness of laptops as a note-taking device. The use of personal laptops and other electronic devices is also distracting to your classmates and instructor so please do not bring these to class or turn them off when attending the class in person.

Notice of Policy on Cheating: Students are expected to be above reproach in all scholastic activities. Students who engage in scholastic dishonesty are subject to disciplinary penalties, including the possibility of failure in the course and dismissal from the university. "Scholastic 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 examination for another student, any act designed to give unfair advantage to a student or the attempt to commit such acts." Regent's Rules and Regulations, Part One, Chapter VI, Section 3.2, Subdivision 3.22. Since scholastic dishonesty harms the individual, all students, and the integrity of the University, policies on scholastic dishonesty will be strictly enforced.

From the UTEP Dean of Student Affairs (http://studentaffairs.utep.edu/Default.aspx?tabid=4386). It is an official policy of the university that all suspected cases or acts of alleged scholastic dishonesty must be referred to the Dean of Students for investigation and appropriate disposition. Any student who commits an act of scholastic dishonesty is subject to discipline. Scholastic 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 examination for another person, any act designed to give unfair advantage to a student or the attempt to commit such acts. "Cheating" includes:

1. Copying from the test paper of another student, engaging in written, oral, or any other means of communication with another student during a test, or giving aid to or seeking aid from another student during a test.
2. Possession and/or use during a test of materials which are not authorized by the person giving the test, such as class notes, books, or specifically designed "crib notes".
3. Using, obtaining, or attempting to obtain by any means the whole or any part of non-administered test, test key, homework solution, or computer program; using a test that has been administered in prior classes or semesters, but which will be used again either in whole or in part without permission of the

instructor; or accessing a test bank without instructor permission.
4. Collaborating with or seeking aid from another student for an assignment without authority.
5. Substituting for another person, or permitting another person to substitute for oneself, to take a test.
6. Falsifying research data, laboratory reports, and/or other records or academic work offered for credit.

Plagiarism means the appropriation, buying, receiving as a gift, or obtaining by any means another's work and the unacknowledged submission or incorporation of it in one's own academic work offered for credit, or using work in a paper or assignment for which the student had received credit in another course without direct permission of all involved instructors. NOTE: This includes cutting-and-pasting and photocopying from online and other materials.

Collusion means the unauthorized collaboration with another person in preparing academic assignments offered for credit or collaboration with another person to commit a violation of any provision of the rules on scholastic dishonesty. If you are found to be cheating or plagiarizing, you will be subject to disciplinary action, per UTEP catalog policy.

Special Accommodations: I will make any reasonable accommodation for students with limitations due to disabilities, including learning disabilities. Please see me personally before or after class in the first two weeks or make an appointment to discuss any special needs you might have. If you have a documented disability and require specific accommodations, you will need to contact the Center for Accommodations and Support Services in the East Union Bldg., Room 106 within the first two weeks of classes. The Center for Accommodations and Support Services can also be reached in the following ways:

Web: http://sa.utep.edu/cass/
Phone: (915) 747-5148 voice or TTY
Fax: (915) 747-8712

Any errors in the above syllabus are subject to correction and all course requirements are subject to revision. Students will be notified in writing of all changes made to this syllabus.