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

Course Number: DRSC 4330
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 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 ICON/ USB Pharma
Catherine Posey, CCRC, COO, Western Sky Medical Research

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.

Format: The course is 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
4-year period. Sample questions would 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 https://app.pro-ficiency.com/user/login
Students will receive this link and login instructions via an email from Pro-ficiency--ACRP's
eLearning platform partner and 2) Course Google Docs Folder containing infographics,
handouts, case studies, and slide presentations.

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 taks, 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 steos 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
conduc 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 that 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 - michael@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%) and
F (< 60%).
Letter grades based on this distribution will then be assigned each student.
Students must complete 15 modules in 9 sessions. Each session must be completed by Saturday (of each session) at 11:59pm.

Course grades will be calculated using the following weights:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
<th>% of Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of Session 1</td>
<td>Completion of eLearning module # 1,2</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 2</td>
<td>Completion of eLearning module # 3,4</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 3</td>
<td>Completion of eLearning module # 5,6</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 4</td>
<td>Completion of eLearning module # 7,8</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 5</td>
<td>Completion of eLearning module # 9,10</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 6</td>
<td>Completion of eLearning module # 11</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 7</td>
<td>Completion of eLearning module # 12</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 8</td>
<td>Completion of eLearning module # 13</td>
<td>10%</td>
</tr>
<tr>
<td>Completion of Session 9</td>
<td>Completion of eLearning module # 14,15</td>
<td>10%</td>
</tr>
<tr>
<td>Final Exam (ELKA)</td>
<td>Covers material from the entire course</td>
<td>10%</td>
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</tbody>
</table>

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

Students must pass 15 eLearning module exams and an Entry Level Knowledge Assessment (ELKA) course exam at the end of the course. In other words, included in the course syllabus are 15 ACRP eLearning modules. Students will need to pass 15 exams via ACRP's eLearning portal which will automatically appear 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 course exam or Entry Level Knowledge Assessment (ELKA). Students will have two (2) chances to pass both 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. All eLearning module exams are pass/fail.
<table>
<thead>
<tr>
<th>Session (Date/ Time/ Instructor)</th>
<th>Module</th>
<th>Session</th>
<th>Pre-Requisites (eLearning)</th>
<th>Pre-reads/Self-Study Resources for Participants</th>
<th>Infographics</th>
<th>Case Studies</th>
</tr>
</thead>
</table>
| **Session 1:**  
Date:  
Monday 6/6_SS  
Wednesday 6/8_IL  
Time: 6-7:30 PM  
Instructor: Laura Herrera, DNP, Sub-I Western Sky Medical Research | 1 | CRC Core Competency Foundations Overview and Roadmap | **ACRP CRC Core Competency Foundations Training Plan**  
**CRC competency development and assessment roadmap** |  |  | No |
| **Session 2:**  
Date:  
Monday 6/13_SS  
Wednesday 6/15_IL  
Time: 6-7:30 PM  
Instructor: Sergio Guerrero, MD Site Engagement Manager ICON/ USB Pharma | 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** |  |  | No |
| **Session 3:**  
Date:  
Monday 6/20_SS  
Wednesday 6/22_IL  
Time: 6-7:30 PM  
Instructor Laura Herrera, DNP, Sub-I Western Sky Medical Research | 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** |  |  | No |
| **Session 4:**  
Date:  
Monday 6/27_SS  
Wednesday 6/29_IL  
Time: 6-7:30 PM  
Instructor Laura Herrera, DNP, Sub-I Western Sky Medical Research | 4 | Clinical Research Relationships, Responsibilities Documents and Processes – Part 2 – Essential Documents |  | **Essential Document Management** | Yes |
| **Session 5:**  
Date:  
Monday 7/4_SS  
Wednesday 7/6_IL  
Time: 6-7:30 PM  
**FDA Guidance – Using a Centralized IRB Review Process** |  |  | No |
| **Session 6:**  
Date:  
Monday 7/11_SS  
Wednesday 7/13_IL  
Time: 6-7:30 PM  
Instructor Laura Herrera, DNP, Sub-I Western Sky Medical Research | 6 | GCP / HSP Check In - Your Questions Answered! | **Ethics and Human Subject Protection: A Comprehensive Introduction eLearning Module**  
**FDA Guidance - Data Retention When Subjects Withdraw Consent**  
**FDA Guidance - Guide to Informed Consent** |  |  | No |
<table>
<thead>
<tr>
<th>Session 4:</th>
<th>Date: Monday 6/27_SS  Wednesday 6/29_IL</th>
<th>Time: 6-7:30 PM</th>
<th>Instructor: Catherine Posey, CCRC, COO, Western Sky Medical Research</th>
</tr>
</thead>
</table>
| Number: 7 | Topic: 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 |
| Session 5: | Date: Monday 7/4_SS  Wednesday 7/6_IL | Time: 6-7:30 PM | Instructor: Laura Herrera, DNP, Sub-I, Western Sky Medical Research |
| Number: 9 | Topic: Subject Safety Management Check-in! |  | · FDA Guidance - AE Reporting  
· ICH e2a Clinical Safety Data Management  
· Safety Management  
Yes |
| Number: 10 | Topic: IP Management and Accountability 101 |  | · Sample IP Management SOP  
· Sample IP Storage Temperature Log  
· IP Management  
Yes |
| Session 6: | Date: Monday 7/11_SS  Wednesday 7/13_IL | Time: 6-7:30 PM | Instructor: Catherine Posey, CCRC, COO, Western Sky Medical Research |
| Number: 11 | Topic: Protocol / GCP Compliance and Monitoring Overview and CAPAs and Root Cause Analysis (RCA) 101 |  | · 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  
· Protocol and GCP Compliance  
· Monitoring Approaches to Decrease Risk and Increase Quality  
No |
<table>
<thead>
<tr>
<th>Session 7</th>
<th>Date: Monday 7/18_SS</th>
<th>Time: 6-7:30 PM</th>
<th>Instructor: Sergio Guerrero, MD, Manager ICON/ USB Pharma</th>
<th>12</th>
<th>Optimizing Study Communications - Best Practices</th>
<th>• eResearch: Managing Clinical Trials in an Electronic Environment eLearning Module</th>
<th>Sites and Sponsors: Root Cause and CAPA eLearning Module</th>
<th>• TransCelerate Protocol Deviation Process Guide</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 8:</td>
<td>Date: Monday 7/25_SS</td>
<td>Time: 6-7:30 PM</td>
<td>Instructor: Sergio Guerrero, MD Site Engagement Manager ICON/ USB Pharma</td>
<td>13</td>
<td>Study Feasibility and Site Selection</td>
<td>• Trial Feasibility and Selection: Their Impact on Accrual</td>
<td></td>
<td>• Understanding Clinical Trial Protocols: Key Considerations for Effective Development &amp; Feasibility Review.</td>
<td>• Site Qualifications</td>
</tr>
<tr>
<td>Session 9:</td>
<td>Date: Monday 8/1_SS</td>
<td>Time: 6-7:30 PM</td>
<td>Instructor: TBD</td>
<td>14</td>
<td>Pulling it all Together: A Day in the Life of a CRC</td>
<td>Entry Level Knowledge Assessment (ELKA) <strong>ACRP's ELKA Exam</strong> The exam must be taken online via ACRP's eLearning portal. Exam will be available until Wednesday August 3. Students will</td>
<td></td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
## 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 university that

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Keynote:</th>
<th>Instructor(s)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/10</td>
<td>6-7:30 PM</td>
<td>TBD</td>
<td>ALL</td>
<td>No</td>
</tr>
</tbody>
</table>

**Graduation Mixer**
- **Date:** Wednesday 8/10
- **Time:** 6-7:30 PM
- **Keynote:** TBD
- **Instructor(s)**: ALL
- **Notes**: No
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 one's self, to take a test; and
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 on-line and other material.

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. Refer to http://www.utep.edu/dos/acadintg.htm for further information

Special Accommodations: I will make any reasonable accommodations 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.