Chair: Tracy Christofero | **GC#6: Course Addition**

Request for Graduate Course Addition

1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.
2. E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
3. ***The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.***

College: Medicine | Dept/Division: CTS | Alpha Designator/Number: CTS 625 | ○ Graded ◉ CR/NC

Contact Person: Todd Davies | Phone: (304) 691-1795

NEW COURSE DATA:

New Course Title: Clinical Research Operations Lab

Alpha Designator/Number: C T S 6 2 5

Title Abbreviation: C l i n i c a l o p e r a t i o n s l a b

(Limit of 25 characters and spaces)

Course Catalog Description: (Limit of 30 words)
This course is a hands on experience in Clinical Research trial operation. The course provides an opportunity for students to work with clinical research professionals on FDA- directed clinical trials.

Co-requisite(s): none | First Term to be Offered: Fall 2017

Prerequisite(s): CTS620 | Credit Hours: 5

Course(s) being deleted in place of this addition (*must submit course deletion form*): none

Signatures: if disapproved at any level, do not sign. Return to previous signer with recommendation attached.

Dept. Chair/Division Head _____	Date _____
Registrar _____	Date _____
College Curriculum Chair _____	Date _____
Graduate Council Chair _____	Date _____

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College: Medicine | Department/Division: CTS | Alpha Designator/Number: CTS625

Provide complete information regarding the new course addition for each topic listed below. Before routing this form, a complete syllabus also must be attached addressing the items listed on the first page of this form.

1. FACULTY: Identify by name the faculty in your department/division who may teach this course.

Todd Davies

2. DUPLICATION: If a question of possible duplication occurs, attach a copy of the correspondence sent to the appropriate department(s) describing the proposal. Enter "***Not Applicable***" if not applicable.

Not Applicable

3. REQUIRED COURSE: If this course will be required by another deparment(s), identify it/them by name. Enter "***Not Applicable***" if not applicable.

Not Applicable

4. AGREEMENTS: If there are any agreements required to provide clinical experiences, attach the details and the signed agreement. Enter "***Not Applicable***" if not applicable.

Not Applicable

5. ADDITIONAL RESOURCE REQUIREMENTS: If your department requires additional faculty, equipment, or specialized materials to teach this course, attach an estimate of the time and money required to secure these items. (Note: Approval of this form does not imply approval for additional resources.) Enter "***Not Applicable***" if not applicable.

Not Applicable

6. COURSE OBJECTIVES: (May be submitted as a separate document)

See Attached Syllabus

7. COURSE OUTLINE (May be submitted as a separate document)

See Attached Syllabus

8. SAMPLE TEXT(S) WITH AUTHOR(S) AND PUBLICATION DATES (May be submitted as a separate document)

See Attached Syllabus

9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)

This course will be taught using a on-on -one mentoring approach and via experiential learning.

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10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)

Evaluation is based on the observation of following the appropriate reporting and documentation for clinical trials as outlined by federal law.

11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE

Not Applicable

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)

see attached

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Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department:
Course Number and Title:
Catalog Description:
Prerequisites:
First Term Offered:
Credit Hours:

Department: Clinical and Translational Sciences
Course Number and Title: CTS 625 Clinical Research Operations Lab
Catalog Description: This course is a hands on experience in Clinical Research trial operation. The course provides an opportunity for students to work with clinical research professionals on FDA-directed clinical trials.
Prerequisites: CTS620
First Term Offered: Fall 2017
Credit Hours: 5

Syllabus
CTS625
Fall Semester
Clinical Research Operations Lab
5 Credit Hours

Course Description

This course is a hands-on practicum focused on the operation of clinical research trials. The course will - provide opportunity for students to work with clinical and research professionals on real FDA-directed clinical research trials.

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Course Director

Todd Davies, PhD (daviest@marshall.edu) 304.691.1795

Course Objectives

The goal of this course will be to provide hands-on experience in clinical research trial operation. By the end of the course the student will:

1. Shadow Clinical Research Coordinators during enrollment and consenting
2. Utilize informatics and Electronic Medical Records to screen patients for specific trials
3. Complete all necessary trial logs
4. Assist in completion of regulatory documentation
5. Conduct data entry protocols

Assessment of Objectives

Objective	Practice of Objective	Assessment Method
Shadow Clinical Research Coordinators during enrollment and consenting	Shadowing of Clinical Research Coordinators during trial specific enrollment. Followed by student performing supervised trial enrollments and consenting	Performance assessment of student conducting enrollment and consenting procedures within HIPAA guidelines
Utilize informatics and Electronic Medical Records to screen patients for specific trials	Using informatics to screen for appropriate patients for a trial under Clinical Research Coordinators supervision	Assessment of proper identification of trial specific patients
Complete all necessary trial logs	Maintaining of appropriate trial logs, daily assessment by Clinical Research Coordinators	Students will be assessed on completeness, accuracy and neatness of trial logs
Assist in completion of regulatory documentation	Filling out of appropriate regulatory paperwork associated with a clinical trial	Students will be assessed on completeness, accuracy and neatness of regulatory forms as well as completion of the IRB submission and reporting process.
Conduct data entry protocols	Enter of trial data into computer based repositories.	Students will be assessed on completeness and accuracy of trial data and compliance with HIPAA and HITECH regulations

Time and Location

This class is an active practicum that requires students to spend 10hrs a week developing hands-on skills in clinical trials operations.

Required Textbooks

There are no required textbooks for this class. The instructor will supply required reading material from regulatory documentation and current scientific literature.

Teaching Methods
This class will be taught using a one-on-one mentoring approach.

Duration
The course will be for a total of 15 weeks, the schedule will be agreed by the mentor and student on a weekly basis.

Assessment

The students will be assessed based on their performance of the various tasks during clinical trials. Each student will be assigned to a Clinical Research Coordinator who will observe and supply feedback on all procedures. Students will be under the supervision of the Director for Research Development and Translation, a certified Clinical Research Coordinator, and the Assistant Dean for Clinical Research, and will receive feedback and performance assessment form each of these individuals..

Grading

This class is a credit no credit class.

Attendance
Attendance at all scheduled course activities is expected.

Class Policies
University policies can be viewed at http://www.marshall.edu/president/board/policies.html.

Academic Dishonesty
Academic dishonesty will not be tolerated. Policy AA-12 defines academic dishonesty and describes the sanctions associated with it.

Inclement Weather
Policy GA-9 describes the policy on weather-related and/or emergency closings and delays. As this is an afternoon class, we will not be affected by delays. To find out if the University is closed, please call Audix at (304) 696-6245.

Students with Disabilities Policy
Students with disabilities are required to prepare a notice either from the Help Center, Myers Hall, or Sandra Clements, PH 117, before a special accommodation can be honored. The link describing this policy is http://www.marshall.edu/disabled.

University Computing Services Acceptable Use Policy
MUBOG Policy IT-1 explains this policy (http://www.marshall.edu/president/board/policies.html).

Cell Phone Use
Cell phone use, including texting, will not be tolerated in the class, unless authorized by the instructor. If special circumstances exist such that a student needs to be in communication with family members or friends during a class, please inform the instructor before the class begins. Permission will be granted on a case-by-case basis and at the sole discretion of the instructor. If a student persists in using cell phones, including texting, after they have been asked to stop, the student will be removed from the class.

Bibliography:

- Nuremberg Code (1948)
  - *"Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10",* Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.
- Declaration of Helsinki (1964, 2013)
  - *World Medical Association Declaration of HelsinkiEthical Principles for Medical Research Involving Human Subjects*. World Medical Association. *JAMA.* 2013;310 (20):2191-2194. doi:10.1001/jama.2013.281053
- Belmont Report (1979)
- ICH E6 Guideline for GCP
- DHHS Regulations (45 CFR 46)
- FDA Regulations (21 CFR 50, 56, 312, 812 …) CFR21 part 11