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: CTS620 (•) Graded ( ) CR/NC

Contact Person: Todd Davies Phone: 304 691-1795

NEW COURSE DATA:

New Course Title: Basic Clinical Research Operations

Alpha Designator/Number: C T S 6 2 0

Title Abbreviation: B a s i c R e s e a r c h O p e r a t i o n s

(Limit of 25 characters and spaces)

Course Catalog Description: (Limit of 30 words)
This course will focus on the operation of clinical research trials, providing an overview of the critical aspects involved in all stages of clinical trials.

Co-requisite(s): none First Term to be Offered: Fall 2016

Prerequisite(s): None Credit Hours: 3

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: CTS620

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)

Lecture: Faculty will present instruction/verbal discourse covering the basics of epidemiology, clinical aspects and molecular aspects of each disorder.
Self-Directed Learning/Independent learning: Selected topics will be introduced by independent learning through faculty-assigned guided reading. Students are expected to use these up-front readings to prepare for subsequent small group discussions.
Small Group Discussion: A learning format in which the students are provided the opportunity to exchange opinions, observations, or ideas among the group to analyze, clarify, or reach conclusions about issues, questions or problems.

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

The course will be split into three sections each of 5 weeks duration for a total of 15 weeks (see attached schedule). An exam will be held at the end of each block, there are also several homework assignments that contribute to the grade, as well as class participation.

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 620 Basic Clinical Research Operations
Catalog Description: This course will focus on the operation of clinical research trial, providing an overview of the critical aspects involved in all stages of clinical trials.
Prerequisites: none
First Term Offered: Fall 2016
Credit Hours: 3

Syllabus
CTS620
Fall Semester
Basic Clinical Research Operations
3 Credit Hours

Course Description
This course will focus on the operation of clinical research trials. The course will provide an overview of the critical aspects of operating a clinical research trial including: contracting, budgeting, patient recruitment, source documentation, data entry and recovery, trial coordination in a clinical setting and the ethics of research on human subjects.

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

Course Objectives
The goal of this course will be to provide an introduction to clinical research trial operation. By the end of the course the student will be able to:

1. Identify the critical aspects of a sponsor contract and budget
2. Articulate the critical aspects of the Belmont Report and ethical ramifications of research on human subjects
3. Create trial logs and screening materials
4. Develop source documentation for use in trial coordination
5. Complete clinical research documentation in accordance with FDA regulation CFR 21 part 11

Assessment of Objectives

Objective	Practice of Objective	Assessment Method
Identify the critical aspects of a sponsor contract and budget	Lecture, Reading Assignment	Exam, homework
Articulate the critical aspects of the Belmont Report and ethical ramifications of research on human subjects	Lecture, Reading Assignment, On-line CITI course	Exam, CITI certification
Create trial logs and screening materials	Discussion, Homework	Exams, homework
Develop source documentation for use in trial coordination	Lecture, Reading Assignment, Discussion	Exam, homework
Complete clinical research documentation in accordance with FDA regulation CFR 21 part 11	Lecture, Reading Assignment, Discussion	Exam, Homework, Group discussion

Time and Location
Unless otherwise indicated in the Curriculum Schedule, class meets for lectures and discussions in the TGRI Conference Room on Tuesdays and Thursdays from 10:00 – 11:30.

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
A number of teaching approaches will be employed in this course.
Lecture: Faculty will present instruction/verbal discourse covering the basics of epidemiology, clinical aspects

and molecular aspects of each disorder.
Self-Directed Learning/Independent learning: Selected topics will be introduced by independent learning through faculty-assigned guided reading. Students are expected to use these up-front readings to prepare for subsequent small group discussions.
Small Group Discussion: A learning format in which the students are provided the opportunity to exchange opinions, observations, or ideas among the group to analyze, clarify, or reach conclusions about issues, questions or problems.

Duration
The course will be split into three sections each of 5 weeks duration for a total of 15 weeks (see attached schedule). An exam will be held at the end of each block.

Assessment
Performance will be assessed via four primary methods, exam, homework and CITI certification and class participation (see schedule table for breakdown). Examinations will cover lecture material, and self-guided and independent learning activities.

Grading

Final course grades will be assigned using the following percentages:
A: 90 and above
B: 80 to 89.99
C: 70 to 79.99
F: 69.99 and below

Attendance
Attendance at all scheduled course activities is expected. **Attendance at discussions is required and no makeup will be available for any missed quizzes**.

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.

Proposed Schedule

Week	Topic	Assignment
	Block One	
1	Introduction to Course and Overview of the Components of Clinical Research Trials	
2	Critical Contract Elements	
3	Clinic Trial Budgets	
4	NIH Contracts	Take Home Exam 1
5	Patient Screening and Recruitment	**Exam 1 due [20%]**
	Block Two	
6	Vulnerable Populations	
7	Ethics of Clinical Trials I	
8	Ethics of Clinical Trials II	
9	GCP Training	CITI Certification
10	**EXAM 2 [20%]**	**Certification Due [10%]**
	Block Three	
11	Source Documentation I	
12	Source Documentation II	
13	Data Collection	
14	HIPAA Training	**Homework Due [15%]**
15	**EXAM 3 [20%]**	

Grade Percentage indicated in [brackets]
Class Participation [15%].

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