INSTRUCTIONS FOR COMPLETION OF THE UAMS GRADUATE SCHOOL COURSE APPROVAL FORM

1. Please save this PDF to your computer for editing.

2. The form has been designed with fields for your responses, and these are indicated in blue and gray shading. Please complete all fields. Use the "tab" key to move between fields. A 'beep' will sound if you attempt to enter a response that contains more characters than is permitted. IF YOU NEED HELP IN ANY OF THE FIELDS, PRESS THE F1 KEY AND A HELP WINDOW WILL OPEN.

3. Print the document, and then obtain the appropriate signatures before submitting the form to the Graduate Office.

COURSE APPROVAL FORM, Graduate School
University of Arkansas for Medical Sciences

This form and attached materials are due in the Graduate School Office on the first Monday of the month. All forms will be submitted to the UAMS Graduate Council Curriculum Committee for review and approval prior to consideration by the Graduate Council.

This form is not required for minor stylistic or editorial corrections to the title or course descriptions. These may be made when revising the catalog copy.

1. **Program:** Department of Biomedical Informatics *Department* | B I O M | *Alpha (Department) Code*

2. **Action proposed** (indicate one or more items): Effective term: Fall 2017

- [X] Add course
- [ ] Eliminate course (No outline needed)
- [ ] Change title
- [ ] Change credit hours from: _____ to _____
- [ ] Change course number from: _____ to _____
- [ ] Change description

3. **Course ID, title and description:**

B I O M		Clinical & Translational
prefix	number	title (20 characters)

Clinical and Translational Research
catalog name (40 characters)

Scheduled offering: [X] Fall [X] Spring [ ] Summer [ ] On demand

To cross list a course, use the Course Cross Listing Form.

Describe the course in sentence form using 50 words or less **as it is to appear in the catalog**. List prerequisites, co-requisites and possible off-site instructional opportunities or requirements.

This course provides an introduction to Clinical and Translational research. Topics focus on environmental forces shaping the direction of the development of new therapeutics in the United States and include clinical and translational research as part of healthcare, the therapeutic development process, relevant federal agencies and regulations, and economic factors.

4. **Justification:**

Justify this change in terms of course needs or curriculum improvement. State the effect of this change on any degree programs. Identify the courses to be eliminated, if any, if this course is approved. (Course Approval Forms must also be submitted for these courses) Identify any existing course or courses that would extensively overlap or be duplicated if the proposed curricular change occurs. Provide statements of concurrence with the change from the chairperson(s) and dean(s) of the programs/areas offering the affected courses.

There will be no change to degree programs.

SYLLABUS

COURSE NUMBER: BIOM _____

COURSE TITLE: Clinical and Translational Research

COURSE DESCRIPTION:

This graduate course provides an introduction to Clinical and Translational research. Topics focus on environmental forces shaping the direction of the development of new therapeutics in the United States and include clinical and translational research as part of healthcare, the therapeutic development process, relevant federal agencies and regulations, and economic factors.

PRE-REQUISITES: none

GENERAL INFORMATION:

CREDITS: 1

SEMESTER: Fall, Spring

LOCATION: Campus and Online (hybrid)

FACULTY: Laura James, MD

SPECIAL ASSISTANCE: Students who believe they may need accommodations in this class based on mental or physical impairments must contact the Students with a disability that need accommodations should contact the Associate Dean for Academic Affairs at (501) 686-5730 to schedule an appointment to discuss your needs. Please make arrangements as soon as possible so accommodations can be made in a timely manner.

COURSE OBJECTIVES:

Upon successful completion of this course, the student is able to:

1. Describe the discovery process for new therapeutics
2. Describe regulations that apply to the pre-clinical phase of drugs, biologics and devices.
3. Describe the regulations that apply to the clinical development phase of new therapeutics.

4. Explain common translational blocks and strategies underway by federal agencies, industry and academia to overcome them.
5. Describe important milestones in the development of clinical trial processes in the United States.
6. Explain the outsourcing of clinical study operations to Contract Research Organizations in the US and in other countries in terms of economic forces.
7. Present the design of a drug, biologic, or device development program from the information contained in the label, clinicaltrials.gov, and publically available information on the internet.

MAJOR TOPICS:

Clinical and translational cycle
History of drug, device and biologic development in the US
Drug discovery (target identification, assay development, lead identification and optimization)
Early research and development for biologics and devices
Chemistry, Manufacturing, and Control (CMC) for drug development
Preclinical testing
Contents and purpose of an Investigational New Drug Application (IND) and Investigational Device Exemption (IDE)
Clinical trial phases and operations
Contents and purpose of a New Drug Application (NDA), PMAs and 510 Ks
FDA regulations for drug development
FDA regulations for Biologic development
FDA regulations for device development
The FDA approval process
Post-marketing requirements and surveillance
Financing biomedical research, drug discovery and development
Training or physician investigators and participation in clinical trials as a clinical investigational site
Life of a therapeutic after patent protection
National Institutes of Health Clinical and Translational Science Award (CTSA) program

ASSIGNMENTS:

Listed below for each week.

Week 1: History of drug, device and biologic development in the US

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 1 and 2

Quiz: Based on application of material in chapter and discussion

Week 2: Drug discovery (target identification, assay development, lead identification and optimization) and Early research and development for biologics and devices

Assignment: Discussion questions

Reading: Articles provided by instructor

Quiz: Based on application of material in readings and discussion

Week 3: Chemistry, Manufacturing, and Control (CMC) for drug development, Preclinical testing

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapter 7

Quiz: Based on application of material in chapter and discussion

Week 4: Contents and purpose of an Investigational New Drug Application (IND)

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapter 7, Title 21 CFR 21CFR Part 312

Quiz: Based on application of material in chapter and discussion

Week 5: Contents and purpose of an Investigational Device Exemption (IDE)

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 7 and 30, Title 21 CFR 812, Title 21 CFR 820

Quiz: Based on application of material in chapter and discussion

Week 6: Human Subject Protection in Clinical Trials, Title 21 CFR Parts 50 and 56, Title 45 CFR part 46

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 4-6, 9 and 14

Quiz: Based on application of material in chapter and discussion

Week 7: Design of Clinical studies

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 18-20, 32

Quiz: Based on application of material in chapter and discussion

Week 8: Understanding Statistics for Clinical Studies

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 21-24

Quiz: Based on application of material in readings and discussion

Week 9: Clinical Research Operations

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 8, 33-35, Articles on site start-up and monitoring

Quiz: Based on application of material in readings and discussion

Week 10: Program management in therapeutic development

Assignment: Discussion questions

Reading: Articles from the literature

Quiz: Based on application of material in chapter and discussion

Week 11: New Drug Application (NDA) Submission and Approval process

Assignment: Discussion questions

Reading: Title 21 CFR 314

Quiz: Based on application of material in readings and discussion

Week 12: Device classification, Premarket Approval (PMA) and 510K Submission and Approval process

Assignment: Discussion questions

Reading: Title 21CFR 862-892

Quiz: Based on application of material in readings and discussion

Week 13: Post-marketing commitments and surveillance

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters

Quiz: Based on application of material in chapter and discussion

Week 14: Financing biomedical research, drug discovery and development

Assignment: Discussion questions

Reading: Gallin and Ognibene Chapters 36-38

Quiz: Based on application of material in chapter and discussion

Week 15: **Project presentations**

Major Project: You will be assigned a marketed therapeutic. Research the label and approval history for the therapeutic. From this information, describe in detail, the development program starting from discovery to the currently marketed product. Each study mentioned in the labeling or approval information, primary and secondary safety and efficacy endpoints and each study's role in the therapeutic development must be addressed. Regulatory approval and marketing in other countries does not need to be included, however significant

studies run outside the US and their role in the therapeutic development program should be described.

TEXTBOOKS:

John I. Gallin and Frederick P Ognibene, Principles and Practice of Clinical Research, Third Edition. Elsevier, Boston Mass, 2012.

EVALUATION:

This is a graded course. Grades will be assigned based on their course average according to the following scale: A (93-100), B (85-92), C(75-84), D(65-74), Fail (lower than 64).

The course average will be comprised of course assignments and the Major project.

Quizzes.....50%
Project.....50%

6. **Program Approvals:**

Fred Prior, PhD, Department of Biomedical Informatics
(Print or type) Chairperson, Academic Department or Area

Fred Prior 10/25/16
(Signature) Chairperson, Academic Department or Area Date

11/17/2016
College Dean (Dean McGehee for College of Medicine) Date

7. **Graduate School Approvals**

Eric C Peterson 11/17/2016
Chairperson, Graduate Council Date

11/17/2016
Dean of the Graduate School Date