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 | D | B | M | I | | | | |
Department *Alpha (Department) Code*

2. **Action proposed** (indicate one or more items): Effective term: Fall 2018

- ■ 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	M	I	G	6	1	?	?	CRI Synthesis
prefix				number				title (20 characters)

Clinical Research Informatics Synthesis
catalog name (40 characters)

Scheduled offering: ☐ Fall ☒ 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.

Students will synthesize graduate work to design, plan and operationalize data collection, management and use for a clinical study. This course is conducted within the context of an ongoing clinical study for which the student will join the team and participate in study operations for the semester.

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.

The breadth and scope of this advanced course provides a level of exploration in data management of clinical studies that is not currently offered by the courses in the clinical research informatics track of the biomedical informatics graduate program.

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.

SYLLABUS

COURSE NUMBER: BMIG 61XX

COURSE TITLE: Clinical Research Informatics Synthesis

COURSE DESCRIPTION:

Students will synthesize graduate work to design, plan and operationalize data collection, management and use for a clinical study. This course is conducted within the context of an ongoing clinical study for which the student will join the team and participate in study operations for the semester.

PRE-REQUISITES: BMIG 6110, BMIG 5011/5012

CO-REQUISITES: BMIG 6010 and 6011 must be taken before or with this course.

GENERAL INFORMATION:

CREDITS: 3 credit hours

SEMESTER: Spring

LOCATION: Campus and Online (hybrid)

FACULTY: Meredith Nahm Zozus, PhD

SPECIAL ASSISTANCE: Students who believe they may need accommodations in this class based on mental or physical impairments must 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 the dissertation, the student is able to:

Draft a Data Management Plan (DMP) and Data Management Plan summary from a clinical study protocol or other study design information.

Evaluate and report differences between (1) your DMP and the actual plan for an ongoing study and (2) the actual plan for the study and accepted best practice.

Perform three or more activities in the role of Clinical Study Data Manager or Clinical Study Informaticist on a study. For each report your experience in terms of (1) application of theory, methods and regulations

in practice, (2) your preparedness to apply established theory, methods and regulations in practice, and (3) existence or lack of established theory and methods to inform practice.

Draft and manage a schedule for the above activities.

Draft an Individual Development Plan (IDP) summarizing remaining gaps in your experience, knowledge and skills with respect to you desired next career step.

MAJOR TOPICS:

The practice of clinical research informatics
Application of theory and methods in practice
Gaps in theory and methods with respect to practice
Integration of research and practice
Roles and responsibilities of clinical research Informaticists on interdisciplinary teams
Management and oversight in clinical research informatics
Quality Management Systems in clinical research informatics

COURSE OUTLINE:

This course meets for one hour weekly. Course learning activities include:

1. Data Management Plan creation and evaluation
2. Participation in three activities on ongoing clinical research projects
3. Project planning and project management of the plan for completing and reporting the course requirements.

In the course meetings, student synthesis work will be presented and discussed. Early in the semester, students will learn about project opportunities available for student participation. Students will select three project activities to undertake for course credit and create a project plan for completing them. Course meetings will be structured around student presentation of student work and progress towards course objectives. All student learning activities will be formally presented in the course meetings. Active participation in discussion about project experience, learnings, and feedback is required. Students will schedule and manage course time slots so that all activities are presented during the semester. Presenting students are responsible for their 15 minute formal presentation as well as for facilitating from 30 to 45 minutes of discussion.

EVALUATION:

Overall Course Grading: There are seven graded components of the course (listed below):

Data Management Plan (DMP) Creation	20%
Data Management Plan Evaluation	20%
Project Activity Report 1	10%
Project Activity Report 2	10%
Project Activity Report 3	10%
Course schedule and schedule management	10%

Final Course Report 20%

The final course report should focus on the totality of the student's synthesis of practice. The final course report should include a statement of the student's philosophy of the practice of Clinical Research Informatics. If the student is a doctoral student the philosophy of practice statement should include the student's views on the relationship of research and practice. The final course report should summarize the student's didactic learning to date and their experience in practice whether received in this course or program or elsewhere and state how the didactic learning and practice experience to date inform and support the student's desired career progression. The final course report should conclude with an analysis of gaps in the student's professional knowledge (the skills assessment from student orientation may be used but should be updated to reflect the student's understanding of knowledge and skills required for their desired career) and an updated Individual Development Plan (IDP) for the student's desired career. The IDP should address all remaining gaps in knowledge and skills. The final course report will be presented in the final weeks of the semester as scheduled by the student.

Graded Project Participation: To assure consistent competency, levels of achievement and management of project, grades are assigned to project activity reports based on the following rubric. The four grading criteria are weighted evenly. Each criterion is rated on the following scale.

Fully Met Independently..... 4 points
Fully Met With Direction..... 3 points
Partially Met.....2 points
Attempted but Not Met..... 1 point
Not Attempted .....0 points

Graded project participation is a formative evaluation of a student's progress toward professional practice or research independence. A passing grade is a 2.0 or above. It is expected that a student's first independent attempt at a research informatics task will require some direction or improvement. The purpose of the grading criteria and rubric is to detect these areas as soon as possible so that progression to independence can occur and so that it occurs consistently throughout the program. Consistent scores in the range of 1-2 or lower are not indicative of successful completion. A student operating across multiple criteria at the "Fully Met With Direction" may successfully complete the course but would strongly be urged to seek further training and practice in the attempted activities.

At the close of each semester, the Project Activity Report evaluations will be retained with the student's IDP and Plan of Work. It is expected that areas in need of improvement are addressed on the following IDP and PoW as needed.

Project Activity Report Grading Rubric		
INSTRUCTOR	An introduction is provided to the Project Activity Report that describes the activity undertaken. The activity is placed in the context of the clinical study and the clinical study is placed in the context of the clinical and translational research cycle.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted

INSTRUCTOR	Relevant theory, methodology, organizational Standard Operating Procedures (SOPs), and regulations are stated. Established best practices are identified.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted
INSTRUCTOR	Gaps between relevant theory, methodology, organizational Standard Operating Procedures (SOPs), and regulations and how the activity was carried out on the project are analyzed. Rational and explanation of project practices is provided.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted
INSTRUCTOR	Barriers and facilitators to completing the project activity are identified and their impact on the activity and project are explained. Barriers and facilitators may include personal, interpersonal, sociological, organizational, technical or other barriers faced.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted
PRECEPTOR	The student completed the activity conscientiously and meticulously with scientific rigor. Problems that occurred were detected, acknowledged, addressed and corrected constructively by the student.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted
PRECEPTOR	Research tasks were carried out with professionalism, respect and consideration for the values, work and ideas of others.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted
INSTRUCTOR	An accurate, concise and well-written project activity report is created and well-presented.	___ Fully Met Independently ___ Fully Met With Direction ___ Partially Met ___ Attempted Not Met ___ Not Attempted

ADDITIONAL RESOURCES:

1. Society for Clinical Data Management (SCDM) Good Clinical Data Management Practices (GCDMP)
2. Rachel Richesson and James Andrews (Eds.), Clinical Research Informatics. Springer, 2012.
3. Meredith Zozus, Managing Research Data. Taylor Francis/CRC Press, 2017.
4. Susanne Prokscha Practical Guide to Clinical Data Management, Third Edition, Taylor Francis/CRC Press 2011.
5. Dixion Rwakasyaguri, How To Become A Clinical Data Manager In 7 Steps, 1st Edition: Mastering the Art of Clinical Data Management in the 21st Century Feb 10, 2016
6. Eleanor McFadden, Management of Data in Clinical Trials, Wiley, 2007
7. Richard K. Rondel and Sheila A. Varley, Clinical Data Management Wiley, 2000.

TEXTBOOKS:

none

Link to UAMS Online Bookstore:
http://uams.textbookx.com/institutional/index.php?action=browse#books/1552684/

5. Program Approvals:

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

Fred Prior — Digitally signed by Fred Prior Date: 2018.02.01 15:44:00 -06'00' — 2/1/2018
(Signature) Chairperson, Academic Department or Area — Date

College Dean (Dean McGehee for College of Medicine) — Date 4/19/2018

6. Graduate School Approvals

S. Andrew James — 4/19/18
Chairperson, Graduate Council — Date

Dean of the Graduate School — Date 4/19/18