University of Arkansas for Medical Sciences
Office of the University Registrar
GUS Course Catalog Form

This form should be used for courses offered at UAMS. If a course addition will change the curriculum for one or multiple degree plans, you will be asked to update a curriculum template for each degree program affected. Please remember to submit a copy of the syllabus with this form.

Course Changes and Additions Submission Timeline

Fall Semester	February 1st (same calendar year)
Spring Semester	September 1st (preceding calendar year)
Summer Semester	December 1st (preceding calendar year)

This request is for a: New Course ☒ Course Change ☐ Course Retirement ☐ (skip to p. 4)

College: Graduate School

Department/Program: Department of Biomedical Informatics

Course Title: Clinical Research Informatics

Course Description: This graduate course presents information-reliant processes in clinical research with an emphasis on major theories, principles, and methods used in practice and inquiry in Clinical Research Informatics.

Course Instructor: Meredith Zozus, PhD

Course Instructor Email: mzozuz@uams.edu Course Instructor Phone: (501) 603-1766

Additional Instructors: None

Click here to enter additional instructor names and email addresses

Click here to enter additional instructor names and email addresses

GENERAL COURSE INFORMATION

First term course will be offered/changed: Fall ☒ Spring ☒ Summer ☐

First year course will be offered/changed: 2017

Meeting dates differ from standard semester? Yes ☐ No ☒

If yes, describe meeting pattern: (i.e. last 4 weeks of semester, 8 Wednesdays beginning 2nd week, etc.)

Grading Basis: Letter Grade Number of Units: 3

If Variable Credit, list the maximum number of units: *Choose an item.*

Component Type: *Lecture*

Repeat for credit? Yes ☒ No ☐

If yes, limit to number of enrollments allowed per student: None

Preferred Catalog Number: *Click here to enter text.*
*Note: Preferred Catalog Numbers are not guaranteed to be used.

ENROLLMENT CONTROLS

PREREQUISITES

Subject Area	Catalog #	Course Title	Course ID (if known)
BIOM	*Catalog #*	Introduction to Biomedical Informatics	*Course ID*
BIOM	*Catalog #*	Fundamentals of managing research data	*Course ID*
BIOM	*Catalog #*	Clinical and Translational Research	*Course ID*
BIOM	*Catalog #*	Human Computer Interaction in Healthcare	*Course ID*

CO-REQUISITES

Subject Area	Catalog #	Course Title	Course ID (if known)
BIOM	*Catalog #*	Information Systems in Clinical Research	*Course ID*
Subj. Area	*Catalog #*	*Course Title*	*Course ID*
Subj. Area	*Catalog #*	*Course Title*	*Course ID*
Subj. Area	*Catalog #*	*Course Title*	*Course ID*

Please list any other non-course prerequisites attached to this course (e.g. minimum GPA, exam, year in program)
Click here to enter text.

Minimum Number of Students to Enroll: No Minimum
Maximum Number of Students who may Enroll: No Maximum

Is enrollment in this course limited to certain groups of students (i.e. PhD students only)? Yes ☐ No ☒

Please describe enrollment limits by groups: No Maximum

Is advisor or instructor consent required for students to take this course? Instructor Consent

INSTRUCTION MODE

Please provide information about the first semester this course will be offered. You will have the opportunity to change this information if this form is provided prior to the last date for scheduling requests.

INSTRUCTION INFORMATION

Instruction Mode: *Online - 75-99% some face/face*

FOR ONLINE COURSES ONLY: Will this course be offered to students out of state? Yes ☐ No ☐

Please select all locations where this course will be taught:

Main Campus ☒ Northwest Campus ☐ UAMS Southwest ☐ Other ☐

If "Other" Location, please describe: *Click here to enter text.*

EXAM AND PROGRESSION

Will the course have a final exam? Yes ☐ No ☒

Will the final exam occur during the normally scheduled course time? Yes ☐ No ☐

Is there a minimum grade required for the student to progress? Not Required

ADDITIONAL INFORMATION

Are any degrees affected by this course addition? Yes ☐ No ☒

If "Yes," please list all degrees affected by this change: *Click here to enter text.*

Does this course address/include:

Service Learning[1]:	Partially ☐	100% ☐	Does not address ☒
Inter-professional Education[2] (IPE)	Partially ☐	100% ☐	Does not address ☒
Cultural competency[3]	Partially ☐	100% ☐	Does not address ☒
Patient-Family Centered Care[4]	Partially ☐	100% ☐	Does not address ☒
Interdisciplinary Education[5]	Partially ☒	100% ☐	Does not address ☐

ADDITIONAL INFORMATION:

Click here to enter text.

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[1] A structured learning experience that combines community service with preparation and reflection. Students engaged in service-learning provide community service in response to community-identified concerns and learn: the context in which the service is provided, the connection between their service and their academic coursework, and their roles as citizens.

[2] Defined as students of two or more professions engaged in learning with, from and about each other.

[3] An ability to interact effectively with people of different cultures and ethnic backgrounds. Comprises four components: Awareness of one's own cultural worldview, attitude towards cultural differences, knowledge of different cultural practices and worldviews, and cross-cultural skills. Developing cultural competence results in an ability to understand, communicate with, and effectively interact with people across cultures.

[4] An approach to the planning, delivery, and evaluation of health care that is grounded in mutually beneficial partnerships among health care providers, patients, and families. It redefines the relationships in health care. The core concepts include: Dignity and respect, information sharing, participation, and collaboration.

[5] Defined as the degree to which individuals have the capacity to obtain, process and understand basic health information and services need to make appropriate health decisions.

COURSE RETIREMENT ONLY – Course Additions and Changes can skip to pg. 5

College: *Choose an item.*
Department/Program: *Click here to enter text.*
Course Title: *Click here to enter the current title.*
Catalog Name and Number: *Click here to enter text.*
Course ID (if known): *Click here to enter text.*

What semester and year will this course be retired? *Click here to enter text.*

Are any degrees affected by this course retirement? Yes ☐ No ☐

If "Yes," please list all degrees affected by this change (updated Curriculum Templates for any degree that will change as a result of this retirement are required to be submitted to the Office of the University Registrar):

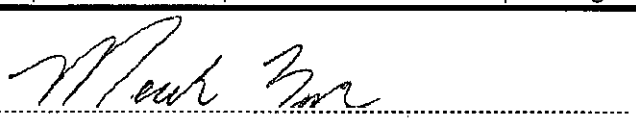
Click here to enter text.

ADDITIONAL INFORMATION:

Click here to enter text.

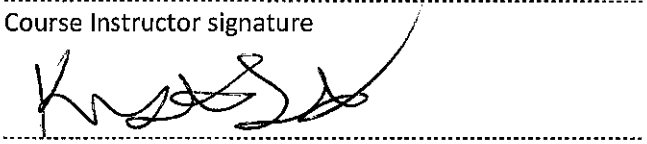
APPROVALS

Proposal will not be processed without all required signatures.



Course Instructor signature

Meredith Zozus, PhD



Associate Dean signature

Enter Associate Dean Name

Today's Date: October 5, 2016

Preparer's Name: Tremaine Williams

Preparer's Email: tbwilliams@uams.edu

Please submit this form and a copy of the syllabus to:
Angela Wilson, Registrar
Email: awilson5@uams.edu
Mail Slot #767
Questions? 501-526-6612

Office use only	**Notes/Follow-up:**
Received: _____	
Entered into GUS ☐	
Entered into Schedule of Courses ☐	
Curriculum Registrar Initials: ___	
Schedule Registrar Initials:___	

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

- ☒ 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 Research Info
prefix				number				title (20 characters)

Clinical Research Informatics
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.

This graduate course presents information-reliant processes in clinical research with an emphasis on major theories, principles, and methods used in practice and inquiry in Clinical Research Informatics.

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.

This course will articulate the scope, goal, and definition of Clinical Research Informatics.

SYLLABUS

COURSE NUMBER: BIOM _____

COURSE TITLE: Clinical Research Informatics

COURSE DESCRIPTION:

This graduate course presents information-reliant processes in clinical research with an emphasis on major theories, principles, and methods used in practice and inquiry in Clinical Research Informatics. Consent of instructor required.

PRE-REQUISITES: Introduction to Biomedical Informatics, Clinical and Translational Research, Human Computer Interaction in Healthcare, Fundamentals of managing research data. Co-requisite: Clinical Research Information Systems.

GENERAL INFORMATION:

CREDITS: 3

SEMESTER: Fall, Spring

LOCATION: Campus and Online (hybrid)

FACULTY: Meredith Zozus

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:

Articulate the scope, goal, and definition of Clinical Research Informatics.

Apply common functionality in clinical study information systems including those supporting Institutional Review Boards (IRBs), interaction with Electronic Health

Records (EHRs), site-based and central Clinical Trial Management Systems (CTMS), Clinical Data Management Systems (CDMS), Interactive Voice Randomization Systems (IVRS), web-based Electronic Data Capture (EDC) systems, Laboratory Information Systems (LIMS), Biobanking systems, and electronic Patient Reported Outcome (ePRO) systems to solve problems and accomplish goals in clinical studies.

Identify and evaluate potential data sources for a given clinical study.

Develop a data management plan using accepted standards and a Quality Management System approach for data collection and processing for a given clinical study.

Create an agenda for a Quality system audit of data collection and management for a clinical study. Draft a comprehensive response to an audit report.

Outline a pharmacovigilance plan from the perspective of a research sponsor for a new therapeutic from Phase II through the first two years of a post-marketing safety commitment. Contrast a Sponsor's pharmacovigilance with safety surveillance performed by regulators.

Describe the major challenges in clinical and translational research and Biomedical Informatics theories, concepts and principles that may be used to address them.

MAJOR TOPICS:

Definition and scope of Clinical Research Informatics
Identification and selection of data sources for research
Information-reliant processes in clinical research including

- Structured protocol representation
- Study feasibility assessment
- Ethics approval and continuing review
- Start-up and management of multi-center studies
- Participant recruitment and consent
- Integration of data from multiple sources
- Study monitoring and safety surveillance
- Management of study operations, e.g., status reporting and site payment
- Biobanking
- Collection of research data in routine care
- Study registration, Results reporting and data sharing
- Pharmacovigilance

Data and practice standards in clinical research
Quality management and control systems in clinical research
Audits and inspections

ASSIGNMENTS:

1. Write an "elevator speech" to explain Clinical Research Informatics to a high school student.
2. Identify two potential data sources for a clinical study and describe how you will evaluate their capability to support the study.
3. Develop a data management plan for a clinical study.
4. Evaluate a data management plan for a clinical study based on the adequacy of the Quality Management System as outlined in the data management plan.
5. Plan to host an audit. Interpret and respond to the audit report.
6. Pick a current challenge in Clinical Research and explain how one or more theories, concepts or principles might be applied to address it. Search PubMed to identify active research in the area.

Week 1: Introduction to Clinical Research Informatics; types of studies and primary versus secondary data use.

Assignment: Write and post an "elevator speech" to explain Clinical Research Informatics to a high school student. Suggest improvements for two posts by fellow classmates.

Week 2: Identifying, assessing, and selecting data sources for clinical studies

Assignment: Identify two potential data sources for a given clinical study. Evaluate their capability to support the study and identify the best data source.

Week 3: Structured Protocol Representation and Study Registration in ClinicalTrials.gov or Health Services Research Projects in Progress (HSRProj.gov)

Assignment: Mark-up a clinical study protocol using the Protocol Representation model. In the mark-up, include tags for ClinicalTrials.gov registration.

Week 4: Study feasibility assessment and ethics approval work and data flow

Assignment: Compare your protocol mark-up to the format and study metadata required by an IRB of your choice. List common steps that occur in site selection and start-up for a clinical study.

Week 5: Start-up and management of multi-center studies; study enrollment and data collection simulation

Assignment: Calculate and graph data collection for two different scenarios of site start-up. For one of the scenarios assume that 80% of the enrollment comes from 20% of the sites and a linear distribution for the rest of the sites.

Week 6: Clinical-research Data standards (controlled terminology and data elements) and public repositories, e.g., Data element and measure repositories (caDSR, USHIK, VSAC, and UMLS)

Assignment: Identify standard data elements and controlled terminologies that are relevant for a given clinical study.

Week 7: Clinical-research specific Data standards cont. (data models and exchange standards)

Assignment: Pick a current challenge in Clinical Research and explain how one or more data standards might be applied to address it.

Week 8: Workflow, data flow, data integration, and cleaning for studies with multiple centers and multiple data sources

Assignment: Identify two potential data sources for a clinical study. Describe the work and data flow for the acquisition, integration, cleaning and data quality assessment.

Week 9: Uses of data for study monitoring and safety surveillance

Assignment: Outline a risk-base monitoring plan for a given study. For the same study, outline a safety surveillance plan. Describe any commonality.

Week 10: Registries

Assignment: Describe two or more data collection and management options for a clinical service that needs a registry to support their application as a Center of Excellence for their clinical specialty. Recommend the optimal option for a given scenario.

Week 11: Biobanking in clinical studies

Assignment: Calculate the cost of a proposed Biobanking plan for a clinical study.

Week 12: Management and Institutional oversight of research and programs of research

Assignment: Draft report shells and designate likely source systems for a given study management or institutional oversight need.

Week 13: Quality management systems in clinical research; technical, managerial and procedural controls

Assignment: Your organization has just been selected as the data coordinating center for a clinical research network. Outline a quality system appropriate for the CRN.

Week 14: Audits and Inspections

Assignment: Write an audit agenda for a given audit. Draft responses to an audit report. Evaluate the responses by two other students.

Week 15: Organizational versus project-specific considerations in managing clinical studies

Assignment: Respond to the discussion board posts asking you to compare and contrast organizational and project-specific needs for given research scenarios.

Major Project: Develop a, overall Data Management Plan for a clinical study. The study will require design of a data collection form for *de novo* data collection for a study, and integration of multiple data sources. You will be asked to evaluate two DMPs created by others.

TEXTBOOKS:

Rachel Richesson and James Andrews (Eds.), Clinical Research Informatics. Springer, 2012.

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices. Publically available at no cost from www.SCDM.org (Use the posted version, the document is updated several times a year.)

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.
Assignments.....60%
Major project.....40%

6. **Program Approvals:**

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

Fred Prior 10/5/16
(Signature) Chairperson, Academic Department or Area Date

10.20.16
College Dean (Dean McGehee for College of Medicine) Date

7. **Graduate School Approvals**

Eric C Pitt 10/20/16
Chairperson, Graduate Council Date

10-20-16
Dean of the Graduate School Date