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: Information Systems in Clinical Research

Course Description: This graduate course covers information systems used in Clinical Research with an emphasis on automation, system functionality, system integration, and information exchange. Common information-reliant and automated processes and methodology are explored.

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*
Subj. Area	*Catalog #*	*Course Title*	*Course ID*
Subj. Area	*Catalog #*	*Course Title*	*Course ID*

CO-REQUISITES

Subject Area	Catalog #	Course Title	Course ID (if known)
BIOM	*Catalog #*	Clinical Research Informatics	*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: *Click here to enter max enrollments.*

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):

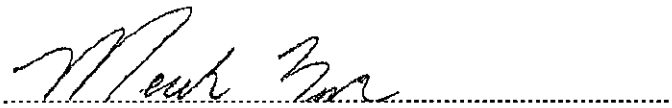
Click here to enter text.

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

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

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

B	I	O	M					Info Sys in Clinical Res
prefix				number				title (20 characters)

Information Systems in Clinical 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 graduate course covers information systems used in Clinical Research with an emphasis on automation, system functionality, system integration, and information exchange. Common information-reliant and automated processes and methodology are explored. Students will hone skills in software lifecycle management to challenges in Clinical Research.

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 is a need to describe the functionality of common types of information systems used in clinical research 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, Biobanking systems, Laboratory Information Systems (LIMS), and electronic Patient Reported Outcome (ePRO) systems.

SYLLABUS

COURSE NUMBER: BIOM _____

COURSE TITLE: Information Systems in Clinical Research

COURSE DESCRIPTION:

This graduate course covers information systems used in Clinical Research with an emphasis on automation, system functionality, system integration, and information exchange. Common information-reliant and automated processes and methodology are explored. Students will hone skills in software lifecycle management to challenges in Clinical Research. Consent of instructor required.

PRE-REQUISITES: Introduction to Biomedical Informatics, Fundamentals of managing research data. Co-requisite: Clinical Research Informatics.

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:

Describe the functionality of common types of information systems used in clinical research 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, Biobanking systems, Laboratory Information Systems (LIMS), and electronic Patient Reported Outcome (ePRO) systems.

Describe methods of system integration and data exchange.

Describe the purpose and information content of data standards supporting information exchange in clinical research.

Suggest appropriate automation of clinical research processes and software functionality needed for the automation.

Write functional specifications for an information system for a particular aspect of a clinical study. Compare and evaluate the functional specifications drafted by others.

Given a research scenario and a selected information system, draft an implementation and evaluation plan. Compare and contrast the plans developed by others.

Describe and manage data system start-up for a given clinical study.

MAJOR TOPICS:

Types of information systems used in clinical research including

- Ethics review submission and management systems
- Contract management systems
- Site-based Clinical Trial Management Systems (CTMS)
- Central (coordinating center) CTMS'
- Enterprise Project Management (EPM) systems
- Web-based Electronic Data Capture (EDC) systems
- Electronic Patient Reported Outcome (ePRO) systems
- Computer Aided Interview (CAI) systems
- Laboratory Information Systems (LIMS) and Biobank Management Systems
- Electronic Health Record (EHR) functionality for research

Automation of clinical research processes
System integration and data exchange methods in clinical research
Implementation of data exchange standards in clinical research

Systems used in the course: REDCap, OpenClinica

ASSIGNMENTS:

1. Describe the major functionality supported by common clinical research information systems.
2. Match system functionality to project needs.
3. Develop an access control matrix for a given study and information system.
4. Compare and contrast system configuration and computer programming.
5. Compare and contrast resources required for implementation and maintenance of Commercial Information Systems versus in-house developed software.
6. Write functional specifications for an information system for a particular aspect of a clinical study. Compare and evaluate the functional specifications drafted by others.
7. Given a research scenario and a selected information system, draft an implementation and evaluation plan. Compare and contrast the plans developed by others.
8. Draft a project plan for implementation of a given data exchange standard.
9. Draft an organizational procedure for access control for a given system.
10. Draft an organizational procedure for change control for a given system.
11. Draft an organizational procedure for system validation.

Week 1: Information Systems used in Clinical Research.

Assignment: Compare and contract functionality of different types of systems.

Week 2: Information Systems used in Clinical Research (continued).

Assignment: Compare and contract functionality of different types of systems.

Week 3: Automation in clinical studies

Assignment: Write functional specifications for appropriate automation of a given clinical research process. Compare and evaluate the functional specifications drafted by others.

Week 4: Software selection in clinical research

Assignment: Draft a software selection plan. The plan must include detailed functionality required.

Week 5: Software implementation and evaluation in clinical research

Assignment: Draft an implementation plan for a commercial information system in a clinical study.

Week 6: Functional specifications.

Assignment: Write functional specifications for an information system for a particular aspect of a clinical study. Evaluate the functional specifications drafted by two other students.

Week 7: Software development and validation.

Assignment: Draft an organizational procedure for software validation.

Week 8: System integration

Assignment: Outline a plan for integrating two or more systems for a given research scenario.

Week 9: System integration (cont.)

Assignment: Compare and contract different approaches using a relevant standard as an example of each approach for moving data between systems.

Week 10: Access control and user support

Assignment: Develop an access control matrix for an EDC system. Draft a plan and estimate resource needs for providing user support.

Week 11: Software selection, implementation, and evaluation for clinical research

Assignment: Draft software selection criteria for specified functionality. Identify and evaluate two products from those advertised on the web. Select one, support your selection and draft an implementation plan.

Week 12: Change control

Assignment: Draft a plan for change control for data systems used in clinical studies.

Week 13: Title 21 CFR Part 11 and traceability

Assignment: Given a research scenario decide if Part 11 applies and draft a compliance plan.

Week 14: Information systems for secondary data use

Assignment: Draft a data transfer plan for a given study.

Week 15: Review and discussion

Major Project: Develop a validation, implementation and evaluation plan for an organizational EDC system.

TEXTBOOK:

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

Other Resources:

Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices. Available 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).

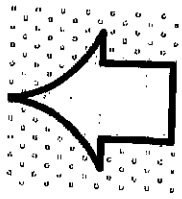
The course average will be comprised of course assignments and the Major project.

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



[signature] 10.20.16
College Dean (Dean McGehee for College of Medicine) Date

7. **Graduate School Approvals**

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

[signature] 10.20.16
Dean of the Graduate School Date