From:	Smith, Randy
To:	Browning, Kristine
Cc:	Sutherland, Sue; Smith, Randy; Griffiths, Rob; Reed, Katie; Miriti, Maria; Duffy, Lisa; Hunt, Ryan; Lorenz, Becky; Rose, Karen
Subject:	Proposal to revise the Master of Clinical Research Program
Date:	Wednesday, March 4, 2026 5:27:55 PM
Attachments:	image001.png

Kristy:

The proposal from the College of Nursing to revise the Master of Clinical Research Program was approved by the Council on Academic Affairs at its meeting on March 4, 2026. Thank you for attending the meeting to respond to questions/comments.

No additional level of internal review/approval is necessary. This action will be included in the Council's next Annual Activities Report to the University Senate (July 2026).

The Office of the University Registrar will work you with any implementation issues.

Please keep a copy of this message for your file on the proposal and I will do the same for the file in the Office of Academic Affairs.

If you have any questions please contact the Chair of the Council, Professor Sue Sutherland (.43), or me.

Randy

THE OHIO STATE UNIVERSITY

W. Randy Smith, Ph.D.
Vice Provost for Academic Programs
Office of Academic Affairs
University Square South, 15 E. 15th Avenue, Columbus, OH 43201
614-292-5881 Office
smith.70@osu.edu
Assisted by:
Katie Reed
Executive Assistant
(614) 292-5672

TO: Randy Smith, Vice Provost for Academic Programs

FROM: Graduate School Curriculum Services

DATE: **1/23/2026**

RE: Proposal to **Revise the Master of Clinical Research (MCR)** in **The College of Nursing.**

The **College of Nursing** is proposing a **Revision to the Master of Clinical Research (MCR) program**.

The proposal was received by the Graduate School on **12/17/2025**. The combined GS/CAA subcommittee first reviewed the proposal on **1/21/2026** and support its review by the Council on Academic Affairs.

THE OHIO STATE UNIVERSITY
COLLEGE OF NURSING

College of Nursing

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December 15, 2025

Dr. Maria Miriti
Associate Dean of Academic Excellence Graduate School
250 University Hall
230 North Oval Mall

Dear Dr. Miriti,

The College of Nursing administrative leadership team is fully supportive of the attached request for a revision of the College of Nursing Master of Clinical Research program. The College graduate studies committee approved this proposal with a unanimous vote (11/20/2025) and the College faculty had a majority quorum (112 yes, 1 no, 99% affirmative) of the eligible voting faculty on December 10, 2025.

Sincerely,

Kristine Browning

Kristine Browning, PhD, APRN-CNP, FAANP
Clinical Professor
Associate Dean for Graduate Programs

Copy:
• Dr. Becky Lorenz, Senior Associate Dean for Academic Affairs and Educational Innovation
• Dr. Karen Rose, Dean

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December 15, 2025

Dr. Maria Miriti
Associate Dean of Academic Excellence Graduate School
250 University Hall
230 North Oval Mall

Dear Dr. Miriti,

The College of Nursing administrative leadership team is fully supportive of the attached request for a revision of the College of Nursing Master of Clinical Research Program.

Sincerely,

Rebecca A Lorenz

Becky Lorenz, PhD, RN
Associate Professor
Senior Associate Dean for Academic Affairs and Educational Innovation

Proposal to Revise the Master of Clinical Research Curriculum
The Ohio State University College of Nursing

Introduction

The Master of Clinical Research (MCR) program is an accredited, interdisciplinary program, offered entirely online and prepares students to excel as administrators, regulatory specialists and other professional roles on clinical research teams. The clinical research industry relies on professionals that are specially trained to navigate the complex world of medical product development and clinical research to ensure safe and effective evidence-based diagnostics, drugs, biologics and devices for the publics' health. The program, originally launched in 2014, was the Masters in Applied Clinical and Pre-clinical Research (MACPR) and interdisciplinary program with Pharmacy. In 2017, the program transitioned to the College of Nursing, and the MS Translational Pharmacology program was retained in Pharmacy. The Master of Clinical Research (MCR) has two specializations: Clinical Research Management (CRM) and Regulatory Affairs (RA). Currently, credit hours for both specializations are 36 credit hours. Since its inception, this program is delivered fully online and is supported by Ohio State Online (OSO).

This curriculum revision proposal is the result of a market analysis with other competitive MCR programs nationwide and faculty review for curricular drift, understanding work force development and necessary employee competencies.

The **goal of this curriculum revision** is to:

1) Align with clinical trial operations and regulation (human research) rather than pre-clinical (non-human research)
2) Update the curriculum to offer cutting-edge courses that better meet the emerging trends in the industry and employer stakeholders
3) Ensure students gain competencies needed for clinical trial certification and be prepared for a wide variety of roles in the clinical trials workforce
4) Reduce credits to remain competitive with other peer programs (reduce from 36 to 30).

Through our analysis, we identified that comparable programs typically require between 32 and 36 credit hours, reducing our program to 30 credits for both CRM and RA specializations will enhance the program's competitiveness. Competitor programs included in the market analysis:

1) George Washington University (MSHS in Clinical Research Administration and Regulatory Affairs)
2) Arizona State University (MS in Clinical Research Management)
3) Drexel (MS in Clinical Research Organization and Management and MS in Clinical Research for Healthcare Professionals)
4) University of North Carolina Wilmington (MS in Clinical Research and Product Development)
5) Rutgers University (MS in Clinical Research Management)
6) Washington University (MS in Clinical Research Management)
7) Campbell University (MS in Clinical Research)
8) Wake Forest University (MS in Clinical Research Management)
9) St. Cloud University (MS in Applied Clinical Research, MS in Medical Device Regulation and MS in Regulatory Affairs and Services)

This proposal includes: 2 proposed new courses, revision of 1 course, and elimination of 5 courses.

Proposed 2 New Courses

Currently, there is redundancy within the pharmacy-related course offerings, and these courses do not adequately address the needs of clinical research professionals. To address this, we propose **adding a new course: Pharmacology for the Non-Clinician**, which will optimize the curriculum and further differentiate our program, as most clinical research graduate programs do not emphasize pharmacology. This content will replace the need for the existing courses that will be dropped (PHR 5010, PHR 7570, and PHR 7580 (See Table 1 for detail of course titles).

We identified a gap in financial management training for clinical trials. While many programs include courses on budgeting and finance, they rarely incorporate leadership development. To fill this gap, we propose **adding a new course: Research Leadership, Administration, and Finance.** This course will strengthen our competitive position by addressing what is widely regarded as the most significant industry need—preparing clinical research professionals to lead and manage research operations.

Finally, as our program is accredited by the Commission on Accreditation of Allied Health Education Programs, the curriculum remains aligned with the Joint Task Force Competency Domains for Clinical Research Professionals, which continue to guide our development (Sonstein et al., 2018; Sonstein et al., 2024).

Revision of 1 course

We propose to revise **MCR 7405: Clinical Research Study and Site Management course to a new title: Clinical Research Study Management and Monitoring**, in order to more accurately reflect course contentStudents who take roles with Clinical Research Organization(s) and pharmaceutical companies are often initially responsible for monitoring and auditing multi-site data; and internal monitoring within sites. To incorporate this level of monitoring, we propose to change the course name so it is inclusive of both site management and industry monitoring. We propose to delete two of the original course objectives and replace with two objectives that better encompass the needed skills of monitoring from the Contract Research Organization(s) and pharmaceutical companies perspective. This is an identified GAP in the curriculum and consistent with the Joint Task Force Clinical Trial Competencies.

Proposed Course Updates and Addition of New Courses with Rationale:

The overall proposal is to **remove 5 courses that are currently offered by Pharmacy and replace them with 2 new courses (see above) and revise 1 course.** This would represent approximately a 25% change to the program's curriculum. **Table 1 details a summary of the revised MCR curriculum.**

Table 1: Description of Revised MCR Curriculum with Rationale for Change, Implementation Timeline and Net Credit Changes

Current Core Curriculum	Course Modification	Current Credits	Track	Rationale for Change	Implementation	Credit Change
Courses with No Change						
MCR 7770: Fundamentals of Medical	No Change	3	CRM* RA#		N/A	N/A

Product Development and Regulation						
NUR 7781: Responsible Conduct of Research	No Change	3	CRM* RA#		N/A	N/A
MCR 7782: Clinical Research Design and Methods	No Change	3	CRM* RA#		N/A	N/A
MCR 7481: Data Management and Informatics in Clinical Research (Clinical Research Management Track)	No Change	3	CRM* RA#	Adding to the RA# Curriculum Plan	AU 2026 for newly matriculated students	+3 for RA#
MCR 7482: Principles of Quality Management for Medical Product Development	No Change	3	CRM* RA#		N/A	N/A
MCR 7599: Culminating Project in Clinical Research	No Change	3	CRM* RA#		N/A	N/A
MCR 7460: Regulatory Strategy and Clinical Trial Reporting (Regulatory Affairs Track)	No Change	3	RA#		N/A	N/A
MCR 7572: Global Regulation of Medical Products (Regulatory Affairs Track)	No Change	3	RA#		N/A	N/A
MCR 7404: Project	No Change	3	CRM*		N/A	N/A

Management for Healthcare and Clinical Research (Clinical Research Management Track)						
Course title and objective changes						
MCR 7405: Clinical Research Study and Site Management	Change course name to Clinical Research Study Management and Monitoring. Modified the course objectives (seen in attached syllabus)	3	CRM* RA#	Identified GAP in the curriculum and consistent with the Joint Task Force Clinical Trial Competencies. Students who take roles with Clinical Research Organization(s) and pharmaceutical companies are often initially responsible for monitoring and auditing multi-site data; and internal monitoring within sites. To incorporate this level of monitoring, we propose to change the course name so it is inclusive of both site management and industry monitoring. Also, we propose to delete two of the original course objectives and replace with two objectives that better encompass the needed skills of monitoring from the Contract Research Organization(s) and pharmaceutical companies perspective.	Autumn 2026, will be optional for currently matriculated students.	N/A
Credit subtotal for CRM arm of the MCR program curriculum without changes		**24**	**CRM***		N/A	N/A
Credit subtotal for RA arm of the MCR program curriculum without changes		**27**	**RA#**		N/A	N/A
New courses						
MCR XXXX: Pharmacology for the Non-Clinician	New Course (replacing existing courses PHR 5010, PHR 7570, and PHR 7580)	3	CRM* RA# (waive for clinicians with pharmacy background such as RN, MD,	Broad pharmacology course to prepare the non-clinician student to be in clinical research professional role. Clinicians will replace this with a 3-credit elective from the RA/CRM curriculum.	Summer 2027, will be optional for currently matriculated students	+3

			pharmacist, etc.)			
MCR XXXX: Research Leadership, Administration, and Finances	New Course	3	CRM*	Identified GAP in the curriculum and consistent with the Joint Task Force Clinical Trial Competencies. Feedback from students and stakeholders requested more knowledge, skills, and attributes in these topics.	Spring 2027, will be optional for currently matriculated students	+3
Courses to be Deleted						
PHR 5010: Fundamentals of Pharmacology	Delete	3	CRM* RA#	MCR XXXX, Pharmacology for the Non-Clinician, better aligns with the Joint Task Force Clinical Trial Competencies and covers essential outcomes that overlap with this course.	Remove AU 2026 (teach out for students currently matriculated)	-3
PHR 7784: Data Analysis and Interpretation in Clinical Research	Delete	3	CRM* RA#	MCR 7782 is more aligned with the Joint Task Force Clinical Trial Competencies and meets the program's needs. There is significant overlap in the objectives for MCR 7782 and PHR 7784.	Remove AU 2026 (teach out for students currently matriculated)	-3
PHR 7570: Pharmaceutical Safety and Risk Management	Delete	3	CRM* RA#	MCR XXXX, Pharmacology for the Non-Clinician, better aligns with the Joint Task Force Clinical Trial Competencies and covers essential outcomes that overlap with this course.	Remove AU 2026 (teach out for students currently matriculated)	-3
PHR 7402: Economic Evaluation of Healthcare Intervention	Delete	3	CRM*	Faculty curriculum evaluation and Joint Task Force Clinical Trial Competencies revealed these topics are not as relevant.	Remove AU 2026 (teach out for students currently matriculated)	-3
PHR 7580: Principles of Safety Pharmacology	Delete	3	RA#	This is a pre-clinical research course that teaches necessary in vitro and animal research required for FDA approval of new drugs; yet our program is concentrated on human-subjects research. The content in PHR 7580 is not necessary for the education of human subjects focused research.	Remove AU 2026 (teach out for students currently matriculated)	-3
				Net credit change	**Implementation**	**Credit Totals**
Net credit change for CRM arm of the MCR program		**-6**	CRM*	**Net reduction of 9 credits for clinicians; 12 credits for non-clinicians. Clinicians will take 3 credit elective from the CRM/RA arm**	**AU 2026**	**30**
Net credit change for RA arm of the MCR program		**-6**	RA#	**Net reduction of 9 credits for clinicians; 12 credits for non-clinicians. Clinicians will take 3 credit elective from the CRM/RA arm**	**AU 2026**	**30**

*Clinical Research Management; #Regulatory Affairs

Assessment

Program and student learning outcome assessments will remain the same in this revised curriculum. The College of Nursing currently has a Systematic Plan of Evaluation (SPE) which guides all assessment and evaluation at the college level consistent with accreditation requirements. Direct assessment measures include yearly Nuventive Improve student learning outcomes, direct evaluation of learning objectives in courses with assignments, including performance in the culminating project course ePortfolio and final project. Students continue to be required to achieve a B- (B minus) or better in all MCR program courses. Indirect measures include: number of applications to the program, quality of the applicant pool (cumulative GPA), admissions to the program (% admitted, % matriculated), student surveys (program satisfaction during enrollment and at graduation), SEIs and course evaluations, student retention and completion rates, enrolled student cumulative GPAs, time-to-degree, exit surveys at graduation, alumni surveys (applicable employment, use of degree) and employer surveys.

MCR New Curriculum Implementation and Transition Plan

Pending approval, this curriculum will be implemented with matriculating students in Autumn 2026. Current students will have the option to transition to the new curriculum or to continue in the established curriculum plan leading to completion of the MCR degree. The proposed MCR curriculum courses that are to be discontinued will be offered until all students who matriculated prior to Autumn 2026 have graduated (PHR 5010, PHR 7784, PHR 7570, PHR 7402, and PHR 7580).

Appendices:

A: Sample Plans of Study

B: Draft syllabi for new courses and MCR 7405 modification

References:

Sonstein SA, Silva H, Jones CT, Bierer BE. Education and training of clinical research professionals and the evolution of the Joint Task Force for Clinical Trial Competency. Frontiers in Pharmacology. 2024;15. doi:10.3389/fphar.2024.1291675

Sonstein S, Brouwer RN, Gluck W, et al. Leveling the joint task force core competencies for clinical research professionals. Therapeutic Innovation and Regulatory Science. 2018, https://doi.org/10.1177/2168479018799291.

Appendix A

MASTER OF CLINICAL RESEARCH

CLINICAL RESEARCH MANAGEMENT

Sample Plans of Study

Autumn Entry – Full-Time, 12-Month Plan

Note: The Full-Time plan is only available to students entering the program in the Autumn semester.

Year 1 - Autumn		Year 1 – Spring		Year 1 - Summer	
Course	Credits	Course	Credits	Course	Credits
MCR 7770 Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR XXXX** Pharmacology for the Non-Clinician (SP)*	3	**MCR 7404** Project Management for Healthcare and Clinical Research (SU, prereq 7782)	3
MCR 7782 Clinical Research Design and Methods (AU)	3	**MCR 7482** Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7481** Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3		
MCR 7405 Clinical Research Study Management & Monitoring (AU, prereq 7770)	3	**MCR XXXX** Research Leadership, Administration, & Finances (SP & SU, prereq 7405)	3		
Total	*12*	*Total*	*12*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum.

**Clinicians (nurses, physicians, pharmacists) will take an elective from the RA curriculum (MCR 7460, MCR 7572)

MASTER OF CLINICAL RESEARCH

CLINICAL RESEARCH MANAGEMENT

Sample Plans of Study

Autumn Entry – Part-Time, 20-Month Plan

Year 1 - Autumn		Year 1 – Spring		Year 1 - Summer	
Course	Credits	Course	Credits	Course	Credits
MCR 7770 Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR XXXX** Pharmacology for the Non-Clinician (SP)*	3	**MCR 7404** Project Management for Healthcare and Clinical Research (SU, prereq 7782)	3
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7481** Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
Total	*6*	*Total*	*6*	*Total*	*6*

Year 2 - Autumn		Year 2 – Spring	
Course	Credits	Course	Credits
MCR 7782 Clinical Research Design and Methods (AU)	3	**MCR 7482** Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3
MCR 7405 Clinical Research Study Management & Monitoring (AU, prereq 7770)	3	**MCR XXXX** Research Leadership, Administration, & Finances (SP & SU, prereq 7405)	3
Total	*6*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum.

**Clinicians (nurses, physicians, pharmacists) will take an elective from the RA curriculum (MCR 7460, MCR 7572)

MASTER OF CLINICAL RESEARCH

CLINICAL RESEARCH MANAGEMENT

Sample Plans of Study

Spring Entry – Part-Time, 20-Month Plan

Year 1 - Spring		Year 1 – Summer		Year 1 - Autumn	
Course	Credits	Course	Credits	Course	Credits
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7770** Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR 7782** Clinical Research Design and Methods (AU)	3
MCR XXXX Pharmacology for the Non-Clinician (SP)*	3	**MCR XXXX** Research Leadership, Administration, & Finances (SP & SU, prereq 7405)	3	**MCR 7405** Clinical Research Study Management & Monitoring (AU, prereq 7770)	3
Total	*6*	*Total*	*6*	*Total*	*6*

Year 2 - Spring		Year 2 – Summer	
Course	Credits	Course	Credits
MCR 7481 Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3	**MCR 7404** Project Management for Healthcare and Clinical Research (SU, prereq 7782)	3
MCR 7482 Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
Total	*6*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum.

**Clinicians (nurses, physicians, pharmacists) will take an elective from the RA curriculum (MCR 7460, MCR 7572)

MASTER OF CLINICAL RESEARCH

CLINICAL RESEARCH MANAGEMENT

Sample Plans of Study

Summer Entry – Part-Time, 20-Month Plan

Year 1 – Summer		Year 1 – Autumn		Year 1 - Spring	
Course	Credits	Course	Credits	Course	Credits
MCR 7770 Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR 7782** Clinical Research Design and Methods (AU)	3	**MCR XXXX** Pharmacology for the Non-Clinician (SP)*	3
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7405** Clinical Research Study and Site Management (AU, prereq 7770)	3	**MCR 7481** Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3
Total	*6*	*Total*	*6*	*Total*	*6*

Year 2 - Summer		Year 2 - Autumn	
Course	Credits	Course	Credits
MCR XXXX Research Leadership, Administration, & Finances (SP & SU, prereq 7405)	3	**MCR 7482** Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3
MCR 7404 Project Management for Healthcare and Clinical Research (SU, prereq 7782)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
Total	*6*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum

**Clinicians (nurses, physicians, pharmacists) will take an elective from the RA curriculum (MCR 7460, MCR 7572)

MASTER OF CLINICAL RESEARCH

REGULATORY AFFAIRS

Sample Plans of Study

Autumn Entry – Full-Time, 12-Month Plan

Note: The Full-Time plan is only available to students entering the program in the Autumn semester.

Year 1 - Autumn		Year 1 – Spring		Year 1 - Summer	
Course	Credits	Course	Credits	Course	Credits
MCR 7770 Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR XXXX** Pharmacology for the Non-Clinician (SP)*	3	**MCR 7460** Regulatory Strategy and Clinical Trial Reporting (SU, prereq 7770)	3
MCR 7782 Clinical Research Design and Methods (AU)	3	**MCR 7482** Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7481** Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3		
MCR 7405 Clinical Research Study Management & Monitoring (AU, prereq 7770)	3	**MCR 7572** Global Regulation of Medical Products (SP, prereq 7770)	3		
Total	*12*	*Total*	*12*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum.

*Clinicians (nurses, physicians, pharmacists) will take an elective from the CRM curriculum (MCR 7404, MCR XXX: Research Leadership, Administration, and Finances)

Autumn Entry – Part-Time, 20-Month Plan

Year 1 - Autumn		Year 1 – Spring		Year 1 - Summer	
Course	Credits	Course	Credits	Course	Credits
MCR 7770 Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR XXXX** Pharmacology for the Non-Clinician (SP)*	3	**MCR 7460** Regulatory Strategy and Clinical Trial Reporting (SU, prereq 7770)	3
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7481** Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3	**MCR 7482** Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3
Total	*6*	*Total*	*6*	*Total*	*6*

Year 2 - Autumn		Year 2 – Spring	
Course	Credits	Course	Credits
MCR 7782 Clinical Research Design and Methods (AU)	3	**MCR 7572** Global Regulation of Medical Products (SP, prereq 7770)	3
MCR 7405 Clinical Research Study Management & Monitoring (AU, prereq 7770)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
Total	*6*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum.

*Clinicians (nurses, physicians, pharmacists) will take an elective from the CRM curriculum (MCR 7404, MCR XXX: Research Leadership, Administration, and Finances)

Spring Entry – Part-Time, 20-Month Plan

Year 1 - Spring		Year 1 – Summer		Year 1 - Autumn	
Course	Credits	Course	Credits	Course	Credits
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7770** Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR 7405** Clinical Research Study Management & Monitoring (AU, prereq 7770)	3
MCR XXXX Pharmacology for the Non-Clinician (SP)*	3	**MCR 7482** Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3	**MCR 7782** Clinical Research Design and Methods (AU)	3
Total	*6*	*Total*	*6*	*Total*	*6*

Year 2 - Spring		Year 2 – Summer	
Course	Credits	Course	Credits
MCR 7572 Global Regulation of Medical Products (SP, prereq 7770)	3	**MCR 7460** Regulatory Strategy and Clinical Trial Reporting (SU, prereq 7770)	3
MCR 7481 Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3
Total	*6*	*Total*	*6*

Courses in Blue are new courses to the MCR curriculum.

*Clinicians (nurses, physicians, pharmacists) will take an elective from the CRM curriculum (MCR 7404, MCR XXX: Research Leadership, Administration, and Finances)

MASTER OF CLINICAL RESEARCH

REGULATORY AFFAIRS

Sample Plans of Study

Summer Entry – Part-Time, 24-Month Plan

Year 1 – Summer		Year 1 – Autumn		Year 1 - Spring	
Course	Credits	Course	Credits	Course	Credits
MCR 7770 Fundamentals of Medical Product Development and Regulation (AU & SU)	3	**MCR 7782** Clinical Research Design and Methods (AU)	3	**MCR XXXX** Pharmacology for the Non-Clinician (SP)*	3
NUR 7781 Responsible Conduct of Research (AU, SP & SU)	3	**MCR 7405** Clinical Research Study Management & Monitoring (AU, prereq 7770)	3	**MCR 7572** Global Regulation of Medical Products (SP, prereq 7770)	3
Total	*6*	*Total*	*6*	*Total*	*6*
Year 2 - Summer		**Year 2 - Autumn**			
Course	Credits	Course	Credits		
MCR 7460 Regulatory Strategy and Clinical Trial Reporting (SU, prereq 7770)	3	**MCR 7481** Data Management and Informatics in Clinical Research (AU & SP, prereq 7782)	3		
MCR 7482 Principles of Quality Management for Medical Product Development (AU, SP, & SU, prereq 7405)	3	**MCR 7599** Culminating Project in Clinical Research (AU, SP, SU)	3		
Total	*6*	*Total*	*6*		

Courses in Blue are new courses to the MCR curriculum.

*Clinicians (nurses, physicians, pharmacists) will take an elective from the CRM curriculum (MCR 7404, MCR XXX: Research Leadership, Administration, and Finances)

Appendix B

THE OHIO STATE UNIVERSITY

Graduate School
College of Nursing
MCR XXXX
Research Leadership, Administration, and Finances
3 credit hours

Course Faculty:

Prerequisites: Enrollment in the MCR program, or permission of instructor.

Course Description

This course explores the strategic, operational, and financial dimensions of leading and managing research programs across the clinical research ecosystem. Students will examine the research leadership landscape including how to build collaborative teams, navigate administrative duties, and adhere to financial management excellence.

The Master of Clinical Research (MCR) program is a member of the Consortium of Academic Programs in Clinical Research (CoAPCR) and has mapped the program curriculum to The Joint Task Force Core Competencies for Clinical Research Professionals.

Objectives

Upon completion of the course, the student will be able to:

1. Integrate principles of leadership, strategic planning, and operational management to effectively direct clinical research teams and oversee the execution of research studies.
2. Evaluate financial management practices, research infrastructure components, and grant administration processes essential to the successful conduct of clinical trials.
3. Analyze and apply principles of change management to lead and sustain innovation and improvement in clinical research environments.

Course Topics

- Strategic Leadership in Research
- Operational Management
- Financial Management
- Personnel Oversight
- Institutional, Sponsor, and Industry Interfaces
- Innovation and Change Management

THE OHIO STATE UNIVERSITY
Graduate School
College of Nursing
MCR XXXX
Pharmacology for the Non-Clinician
3 credit hours

Course Faculty:

Prerequisites: Enrollment in the MCR program, or permission of instructor.

Course Description

Importance on advanced knowledge in pharmacology in relation to the Clinical Research Professional (CRP) role across healthcare settings. Emphasis is placed on the CRP's role in ensuring safe and effective medication use, evaluating drug interactions, and supporting pharmacovigilance throughout the research process.

The Master of Clinical Research (MCR) program is a member of the Consortium of Academic Programs in Clinical Research (CoAPCR) and has mapped the program curriculum to The Joint Task Force Core Competencies for Clinical Research Professionals.

Objectives

Upon completion of the course, the student will be able to:

1. Explain fundamental principles of drug actions, including how drugs affect the body and how the body affects drugs.
2. Assess pharmaceutical safety in clinical trials, including adverse drug reactions and limitations in detection.
3. Apply pharmacological principles in discussing novel or emerging therapeutic strategies through clinical trials exploration.

Course Topics

- Fundamentals of Pharmacological Mechanisms
- Medication Administration in Clinical Research
- Drug Interactions and Contraindications
- Safety Analysis in Clinical Trials
- Role of Clinical Research Professional (CRP)
- Pharmacovigilance and Post-Marketing Surveillance

THE OHIO STATE UNIVERSITY
Graduate School
College of Nursing
MCR 7405
Clinical Research Study Management and Monitoring
3 credit hours

Course Faculty:

Prerequisites: Enrollment in the MCR program, or permission of instructor.

Course Description

Fundamental principles of clinical research operations from study site selection to study closure from the perspective of sponsors and clinical research sites including an introduction to database design, management, quality assurance and reporting for site and sponsor operations

The Master of Clinical Research (MCR) program is a member of the Consortium of Academic Programs in Clinical Research (CoAPCR) and has mapped the program curriculum to The Joint Task Force Core Competencies for Clinical Research Professionals.

Objectives

Upon completion of the course, the student will be able to:

1. Appraise the requirements for the launch of new clinical studies from the perspective of the sponsor and study site.
2. Generate a plan for clinical trial enrollment, recruitment, and retention of study participants.
3. Apply regulatory, ethical, and quality standards to clinical trial site selection, initiation, and study oversight.
4. Critically evaluate the role of clinical research associates (CRAs) in ensuring trial integrity and compliance in keeping with sponsor responsibilities.

Course Topics

- Principles of Clinical Research Monitoring
- Regulatory Requirements/Good Clinical Practice (GCP)
- Monitoring Visits and Reporting
- Quality Assurance and Control
- Standard Operating Procedures for study operations
- Monitoring and auditing clinical trials
- Investigator and Site Engagement
- Site qualification and selection
- Site initiation and study start-up
- Recruitment planning and implementation

- Informed consent process
- Daily conduct and operations of clinical trials
- Adverse event reporting processes
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