

PROGRAM MODIFICATION PROPOSAL FORM

Name of Institution: **Medical University of South Carolina College of Medicine**

Briefly state the nature of the proposed modification (e.g., adding a new concentration, extending the program to a new site, curriculum change, etc.): **Proposing a dual degree for MD/MSCR**

Current Name of Program (include degree designation and all concentrations, options, and tracks):
No dual degree exists: the MSCR and MD are offered as separate degree programs

Proposed Name of Program (include degree designation and all concentrations, options, and tracks):
MD/MSCR (Master of Science in Clinical Research) Dual Degree Program

Program Designation:

- Associate's Degree Master's Degree
 Bachelor's Degree: 4 Year Specialist
 Bachelor's Degree: 5 Year Doctoral Degree: Research/Scholarship (e.g., Ph.D. and DMA)
 Doctoral Degree: Professional Practice (e.g., Ed.D., D.N.P., J.D., Pharm.D., and M.D.)

Does the program currently qualify for supplemental Palmetto Fellows and LIFE Scholarship awards?

- Yes
 No

If No, should the program be considered for supplemental Palmetto Fellows and LIFE Scholarship awards?

- Yes
 No

Proposed Date of Implementation: Jan 1, 2020

CIP Code: **51.1201**

Current delivery site(s) and modes: Both degrees comprising this proposed dual degree are offered as traditional education degree programs at MUSC.

Proposed delivery site(s) and modes: **MUSC**

Program Contact Information (name, title, telephone number, and email address):

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Institutional Approvals and Dates of Approval:

1. College of Medicine Undergraduate Curriculum Committee: January 12, 2018
2. College of Graduate Studies Curriculum Committee: January 16, 2018
3. MUSC Education Advisory Council: August 22, 2019
4. MUSC Provost's Council: September 16, 2019
5. BOT approval: October 10, 2019

Background Information

Provide a detailed description of the proposed modification, including target audience, centrality to institutional mission, and relation to strategic plan.

MUSC proposes offering a dual degree, combining two existing CHE-approved degrees: MD degree and the Master of Science in Clinical Research (MSCR). Currently, the only dual degree option for medical students interested a career in medical science is the MD/PhD. The MD/PhD degree program is highly selective, and the time required to complete the dual degree is 8-10 years.

The proposed MD/MSCR will provide any medical student with an interest in acquiring core competencies in clinical research the opportunity to earn a dual degree without markedly extending their training time. It is expected that most students will complete the MD/MSCR in five years (vs four years for the MD only). *Exceptional students could complete the dual degree in four years by taking the MSCR courses during the four years of medical school.* MSCR courses are offered online to best accommodate medical students' schedules.

The dual degree will facilitate the ability for the two-degree programs to be offered to students simultaneously. Currently, if a medical student desires to earn the MSCR degree, s/he must take a leave of absence from the MD program to enroll in the MSCR program, and once s/he completes that training, re-enroll in the MD program (as MUSC does not allow students to be enrolled in two-degree programs simultaneously). With the proposed dual degree, the student can take MSCR-related courses and MD-related courses in the same semester.

The MD/MSCR degree aligns with MUSC's mission as it prepares physicians to participate in biomedical clinical research, thus advancing new knowledge.

Assessment of Need

Provide an assessment of the need for the program modification for the institution, the state, the region, and beyond, if applicable.

The proposed MD/MSCR dual degree will meet two needs: first, it will provide medical students research training so that they can extend the population of physicians with clinical research skills, which is critical to advancing scientific knowledge in healthcare. The National Institutes of Health and the National Research Council (US) Committee for Monitoring the Nation's Changing Needs for Biomedical, Behavioral, and Clinical Personnel recognize the need for clinical research workforce and recommend training programs for physicians to acquire the skills necessary for clinical investigation.

Second, medical students across the country face greater competition in matching into various residencies, due largely to declining supply of training sites. Having a clinical research degree to complement a medical degree will make the graduating student a more competitive applicant for the residency of his/her choice.

Transfer and Articulation

Identify any special articulation agreements for the modified proposed program. Provide the articulation agreement or Memorandum of Agreement/Understanding.

N/A

Description of the Program

Students will continue to enter the College of Medicine only through the traditional MD degree pathway and then apply to the dual degree program. A student can begin the dual degree program at any semester after successfully completing the year 1 fall semester (table below shows all students starting in spring for clarity of projecting revenue). There is no cap on the number of medical students who can enroll in the MD/MSCR degree program. It is expected that by 2024, approximately 10 new students will be enrolled. It is further estimated that each new MD/MSCR student will complete the MSCR portion of the degree in one year, though the student is permitted to progress at his/her own pace.

Projected Enrollment						
Year	Fall Headcount		Spring Headcount		Summer Headcount	
	New	Total	New	Total	New	Total
2020			2	2	2	2
2021	2	2	4	4	4	4
2022	4	4	6	6	6	6
2023	6	6	8	8	8	8
2024	8	8	10	10	10	10

Explain how the enrollment projections were calculated.

Based on historic numbers of students who elect to pursue the MSCR (taking a leave of absence from the MD to do so), we anticipate that interest will grow as the opportunity is made more readily available.

Curriculum

Attach a curriculum sheet identifying the courses required for the program.

The courses required for the dual degree are the sum of the courses required for the MD and MSCR degree separately. There is no elimination of courses from either degree with the dual degree structure. The courses for the MSCR degree are described in the next section. This degree program, and the MD degree program, are both previously approved by the CHE.

Curriculum Changes

Courses Eliminated from Program	Courses Added to Program	Core Courses Modified
None	All MSCR courses for new MD/MSCR dual degree seeking students, see Appendix	None

None	All current MD courses are required in the MD/MSCR dual degree program., see appendix.	None

New Courses

List and provide course descriptions for new courses.

MSCR Curriculum

Courses can be taken in variable order, with the exception of MCR 750, Ethical Issues in Clinical Research, which the newly enrolled dual degree student must take the first semester s/he is in the program. The order of all other courses below better ensures that any student that elects to “stop out” of the dual program would be more likely to have completed the required courses to earn the CHE approved Certificate in Clinical Research, even if s/he did not earn the MSCR. Courses with an **asterisk (*)** are eligible to count for the 19 required credit hours for the Certificate.

MCR 750-01 Ethical Issues in Clinical Research* - Required for the first semester of all MD/MSCR students. An emphasis will be placed on the ethical issues associated with clinical research and practice. The focus of the class will be the review of the competencies involved in the conduct of ethically responsible research. The process of assessing ethical issues in research and study will be described. The ethical considerations in study design; study implementation, data management, data analysis, data Interpretation and results presentation and publication will be described. 1 credit hour

MCR 700-01 Clinical Biostatistics* -An introduction to basic and intermediate statistical techniques used to analyze and interpret data in health sciences and related fields. Emphasis is on applications of these methods, with just enough derivation to understand the procedures. Topics include descriptive statistics, graphical methods and probability with applications to epidemiology, discrete and continuous distributions, inference on means, nonparametric methods, and inference on proportions, contingency tables, correlation, analysis of variance, linear regression, logistic regression, and survival analysis. Students will not be expected to run computer programs but will learn how to read printout in order to interpret analytical results. 3 credit hours

MCR 731-01 Critical Review of the Literature*- It is assumed that students in this class have a solid foundation in research design and both parametric and nonparametric statistics. An emphasis will be placed on the competencies and processes necessary to review the scientific literature. In particular, the students will review the published and unpublished literature associated with clinical research results. The focus of the class will be the review of the types of scientific and clinical research manuscripts papers and reports produced from different study approaches. 2 credit hours

MCR 736-01 Clinical Epidemiology* - This course provides an introduction to the discipline of epidemiology and its application to public health research and practice. The course is designed to provide a conceptual foundation for epidemiologic research and application, especially study designs, quantitative concepts and methods, analysis, and interpretation. 3 credit hours

MCR 724-01 Introduction to Clinical Trials* - An emphasis will be placed on the concepts, study designs and procedures used in the implementation of clinical trials research studies. The methodology and process used to access and analyze data as well as the collection of data will be described. 3 credit hours

MCR 732-01 Comparative Effectiveness Research* - This course explores the scope of outcomes studies for evaluating the effectiveness of medical care by emphasizing the development of study designs matched to the research question. The course explores frequently used observation study designs, techniques for evaluating and selecting health outcomes measures, and analytical approaches appropriate to conducting health outcomes research. This course will also cover the approaches used for interpretation and translation of CER data through decision models to compare the cost effectiveness of treatments. 3 credit hours

MCR 789-07 Special Topics (S): Industry/Regulatory* -The course focuses on the conduct of clinical research, whether an investigator-initiated study or participation as a site in an industry sponsored clinical trial. It will present in detail all aspects of clinical research including assessment of opportunities and feasibility, building a budget, negotiating contracts, managing regulatory requirements, and understanding intellectual property. 2 credit hours

MCR 752-01 Team Science in Clinical Research* - An emphasis will be placed on the competencies and processes associated with the concepts of team science in translational research necessary to review the scientific literature. Solving complex societal problems (e.g., environment, poverty, cancer, healthcare) requires the integration of specialized knowledge bases. 1 credit hour

MCR 789-20: Introduction to Grant Writing for Clinical and Translational Research* - The course will function as an interactive description of the research grant mechanisms, application process, review process and implementation. The different types of grants will be presented and the details of the application and peer review. The source of funding will be described. Students will learn an overview of the types of grants, potential funding sources, how to get started and resources available at MUSC. 1 credit hour

MCR 738-01 Clinical Research Introductions - This course provides students with the basic structure of clinical research, mentorship, resources for professional research available throughout the campus. Emphasis will be placed on a variety of clinical research conducted on MUSC's campus. 1 credit hour

MCR 746-01 Informatics and Data Management for Clinical Research* - This course is intended to introduce clinical researchers to research oriented data management and related basic topics in Informatics. Students taking this course will learn about basic concepts in relational database design, modern research data capture tools, clinical data warehousing, security risks and mitigations, privacy issues in electronic data, data standards, data mining and other related topics. Students will get hands-on experience with using modern database tools to solve specific scientific problems by attending the course labs. 2 credit hours

MCR 789-03 ST: Regression Analysis for Clinical Research* - Regression analysis is at the heart of statistics, and a sound knowledge of regression methods will serve students well as they design and conduct research projects. We begin with simple linear regression and then consider extensions such as multiple predictors, nonlinear effects, categorical predictors, and interactions. Students will learn to evaluate model fit using statistics such as t, F, and R² in addition to informal analysis based on observable data patterns. We will rely heavily on graphical representations of the data and make use of plots of regression residuals. Concepts and techniques of regression analysis will be taught based on carefully developed examples. This course is intended for anyone involved in analyzing data, but who does not specialize in statistics. We will use computer software (mainly SAS) to examine data output, but students will only be required to read and understand the output. Students are not responsible for computer programming. 2 credit hours

MCR 789-04 ST: Community Engagement Research*- This course provides a foundation for incorporating the principles and methods of CE in the development of community-academic research partnerships and implementing best practices of CEnR. Topics include social determinants of health, ethics and responsible conduct in CEnR, and strategies to engage communities across phases of the research process. 1 credit hour

MCR 789-32 ST: Leadership* - This course introduces the major historical and contemporary theories of leadership in the workplace with emphasis on the principles and application of leadership skills. The course will include the study of organization structures, principles, techniques and processes as they relate to practice in and management of health services and research organizations. Students should gain a better understanding of organizational behavior issues such as motivation, leadership, communication, interpersonal conflict, group dynamics, organizational structures, and meeting procedures. 2 credit hours

MCR 789-08 ST: Core Clinical Research Training - This course prepares participants to coordinate cost-effective health care research which protects the rights and safety of human subjects, achieves recruitment and retention outcomes and contributes to the science of health care. Participants completing the training will be prepared to coordinate research studies in compliance with the Good Clinical Practice Guidelines and federal regulations concerning human subject research. All participants of this course are required to take the CITI MIAMI Good Clinical Practice as a co-requisite. 1 credit hour

MCR 789-02 Innovation in Clinical Researcher Placement - Innovation has become an important component of academic and scholarly activities and, as such, achievements in innovation should be recognized as essential part of the academic clinical research role, as well as a consideration for promotion and tenure for the academician in clinical research. Metrics and recognition in research, education, clinical services all covered in the course. 1 credit hour

MCR 789-13 ST: Contemporary Topics Seminar - The seminar was created to meet the thematic area of the core competencies in cross disciplinary training for student awareness of current issues in medical education and to focus on contemporary research study designs and techniques for application in patient populations. 1 credit hour

MCR 970 Research - This is a varied credit hour research course determined by the student and mentor. A contract between the two includes material covered and deliverables at the end of the semester. Variable, 1 – 10 credit hours

Similar Programs in South Carolina offered by Public and Independent Institutions

Identify the similar programs offered and describe the similarities and differences for each program.

Program Name and Designation	Total Credit Hours	Institution	Similarities	Differences
None in SC				
		Emory University	Similar competencies taught	Less flexible curriculum; students can begin the dual degree only after Yr1 medical school
		Morehouse Univ	Similar competencies taught	Less flexible curriculum; students can begin the dual degree only after Yr1 medical school
		Univ of Virginia	Similar competencies taught	Less flexible curriculum; students can begin the dual degree only after Yr3 medical school

Faculty

State whether new faculty, staff or administrative personnel are needed to implement the program modification; if so, discuss the plan and timeline for hiring the personnel. Provide a brief explanation of any personnel reassignment as a result of the proposed program modification.

The MD-MSCR will not require any institutional changes in faculty. The College of Medicine Dean's Office existing administrative units will oversee the program. The current administrative structure will support the program. The College of Medicine's Office of Students Affairs, the Associate Deans for Student Affairs and the Associate Dean of Career Planning, will oversee implementation of the structured advising plan including academic advising, career advising, and program application preparation. The MSCR faculty in the College of Graduate Studies will provide the education relevant to the MSCR, as specified in curriculum and will advise students in the research projects.

Resources

Identify new library, instructional equipment and facilities needed to support the modified program.

The proposed MD/MSCR will be sufficiently supported by existing learning resources and equipment. No additional resources are needed.

Library Resources:

Equipment:

Facilities:

Impact on Existing Programs

Will the proposed program impact existing degree programs or services at the institution (e.g., course offerings or enrollment)? If yes, explain

Yes

No

Financial Support

Estimated Sources of Financing for the New Costs						
Category	1st	2nd	3rd	4th	5th	Total
Tuition Funding	\$25,972	\$51,944	\$77,916	\$103,888	\$129,860	\$389,580
Program-Specific Fees						
Special State Appropriation						
Reallocation of Existing Funds						
Federal, Grant, or Other Funding						
Total	\$25,972	\$51,944	\$77,916	\$103,888	\$129,860	\$389,580
Estimated New Costs by Year						
Category	1st	2nd	3rd	4th	5th	Total
Program Administration and Faculty and Staff Salaries	\$23,087	\$23,486	\$23,891	\$24,305	\$24,725	\$119,494
Facilities, Equipment, Supplies, and Materials						
Library Resources						
Other (specify)	\$1,015	\$1,030	\$1,046	\$1,061	\$1,077	\$5,229
Total	\$24,102	\$24,516	\$24,937	\$25,366	\$25,802	\$124,723
Net Total (i.e., Sources of Financing Minus Estimated New Costs)	\$1,870	\$27,428	\$52,979	\$78,522	\$104,058	\$264,857

Budget Justification

Provide a brief explanation for all new costs and sources of financing identified in the Financial Support table.

There are no new costs associated with the proposed MD/MSCR dual degree, as the dual degree will function with the same budgets as the two separate degree programs currently in place. Rather, the dual degree will facilitate the ability for the two-degree programs to be offered to students simultaneously. Currently, if a medical student desires to earn the MSCR degree, s/he must take a leave of absence from the MD program. With the proposed dual degree, the student can take MSCR-related courses and MD-related courses in the same semester.

The cost to the student to earn the MSCR degree is currently (for AY 19-20) \$6,887 per semester for in-state students, and can be completed in three semesters, summing to **\$20,661**. To facilitate clear delineation for education costs and appropriate transfer of tuition funds between the College of Medicine (for the MD education) and the College of Graduate Studies (for the MSCR education), the cost of pursuing the MD/MSCR dual degree will be a one-time fee of \$20,661 (regardless if the student is in-state vs out of state) when they enroll in the MD/MSCR (which is in addition to the medical school tuition and fees the student would already incur). The administrative indicator of the newly enrolled student is the course MCR 750, Ethical Issues in Clinical Research (1 cr), to which the fee above will be attached.

If a student elects to stop pursuing the dual degree in the same academic year in which s/he started it, a full refund of the fee will be made. If s/he transitions out of the dual degree after the academic year in which s/he enrolled in it, the fee will not be refunded, though the student has the opportunity to earn a Certificate in Clinical Research (an approved Certificate by the CHE) if s/he has completed the courses comprising it, all of which are MSCR courses.

The revenue for the dual degree program includes the total tuition cost for the MSCR (\$20,661) minus administration & service costs incurred by the College of Medicine (which is the primary home college for all such students). Those Administrative and Services costs incurred by the College of Medicine is \$7,675 per student if the student extends his/her education time by one year. Therefore, the revenue provided to the College of Graduate Studies for the dual degree seekers, as shown in the table above (\$20,661-\$7,675) is \$12,986 per student. The table shows the revenue projection based on 2 students in year 1 and an additional two students each year thereafter.

The expenses incurred are a percentage of an administrative assistant's time and a percentage of instructional faculty time. Other costs are associated with additional learning materials and support for poster presentations for students.

Evaluation and Assessment

The dual degree program will not be assessed separately from methods used for assessment of each of the degree programs (MD and MSCR) separately; the dual degree program's purpose is to assist students in completing both of these desired degrees without having to withdraw from the MD degree to enroll in the MSCR degree. Each of those programs' assessment plans has been reviewed and approved by CHE in prior program applications and are not repeated here.

Will any the proposed modification impact the way the program is evaluated and assessed? If yes, explain.

- Yes
 No

Will the proposed modification affect or result in program-specific accreditation? If yes, explain; and, if the modification will result in the program seeking program-specific accreditation, provide the institution's plans to seek accreditation, including the expected timeline.

- Yes
 No

Because only currently enrolled MD students will be permitted to enroll in the MD/MSCR dual degree, the students would already be enrolled in an accredited (LCME) medical degree program. Including the dual degree program in MUSC's catalog of available degree programs does not impact LCME accreditation of our medical school.

Will the proposed modification affect or lead to licensure or certification? If yes, identify the licensure or certification.

- Yes
 No

Because only currently enrolled MD students will be permitted to enroll in the MD/MSCR dual degree, the students would already be pursuing eligibility for licensure; enrolling in the dual degree does not affect or alter the existing licensure requirements.

Explain how the program will prepare students for this licensure or certification.

If the program is an Educator Preparation Program, does the proposed certification area require national recognition from a Specialized Professional Association (SPA)? If yes, describe the institution's plans to seek national recognition, including the expected timeline.

- Yes
 No