

MASTER OF SCIENCE IN CLINICAL RESEARCH METHODS

with a concentration in Pre-Surgical Training

OVERVIEW

This is a 58 credit, 2-year, full-time curriculum designed for the recently graduated MD to pursue before entering a traditional training track. The program will educate the student in the process and methods of clinical research, further their surgical knowledge and teach clinical skills necessary for a successful surgical internship. The student would be a resident of the New Orleans area and pursue the curriculum full time.

SAMPLE COURSE SCHEDULE

			Year 1	Year 2	
			Credits	Credits	
<u>SUMMER SEMESTER</u>					
MSCR	6420	Responsible Conduct of Research	1		
MSCR	6430	Topics in Clinical Research	3		
BIOS	6030	Introductory Biostatistics	3		
MSCR	7300	Pre-Surgical Program	3.5	3.5	
Total			10.5	3.5	
<u>FALL SEMESTER</u>					
EPID	6030	Principles of Epidemiology	3		
MSCR	6450	Molecular Medicine		4	
BIOS	6230/40	Computer Package	1		
MSCR	7150	Journal Club/Seminar	1	1	
MSCR	7300	Pre-Surgical Program	4.75	5	
Total			9.75	10	
<u>SPRING SEMESTER</u>					
MSCR	6439	Protocol Design and Writing		3	
BIOS	6040	Intermediate Biostatistics		3	
GHSD	6030	Health Sys Admin & Mngt	3		
MSCR	7080	Cultural Competence		3	
MSCR	7150	Journal Club/Seminar	1	1	
MSCR	7300	Pre-Surgical Program	5.75	4.5	
Total			9.75	14.5	
OVERALL TOTAL			30	28	58

COURSE DESCRIPTIONS

MSCR 6420 Responsible Conduct of Research 1.0

This course will cover basic principles of bioethics and their specific application to clinical research. Special attention will be paid to the ethical obligation of the researcher to the participant within the broader framework of patient care and the ethics of caring. Specific challenges of vulnerable populations and research in a global community will also be considered. This course will also cover differences between clinical research and clinical practice, responsibilities regarding data records, data ownership, collaborative and multi-site issues and authorship. Substantive information will be provided about how to conduct clinical research in an ethical manner, especially in the complex and competitive research environment. This course will define research misconduct, falsification and fabrication, with numerous examples to assist in areas that may not be regulatory. Conflict of interest issues present some of the most complex and potentially volatile challenges in the area of clinical research, they will be covered as well.

BIOS 6030 Introductory Biostatistics 3.0

Introduction to statistical methodology in the health field. Topics covered include presentation of data (graphs and tables), descriptive statistics, concepts of probability, estimation of parameters, hypothesis testing, simple linear regression, correlation, and the analysis of attribute data. The course is recommended for students needing a firm foundation in statistical methods either for their careers or for preparation for further quantitative courses.

MSCR 6430 Topics in Clinical Research 3.0

In this course, students will study IRB relations and regulations, discuss the required elements in a clinical research contract and the responsibilities of the clinical researcher, identify effective use of research personnel, and develop negotiating skills to facilitate support for clinical research. The course will also encompass the principle of randomization and "intention-to-treat" analysis in experimental studies, integration of clinical trials and lab support, specimen collections and laboratory problem based learning. A researcher/clinician centric insight into the logistics of technology transfer and intellectual property (IP) development will be studied. The practical aspects of technology transfer in an academic context will be investigated. Discussed topics will include local academic tech transfer policy, related procedures and available resources. Career pathways and opportunities open to the clinical researcher in the academic and private sector will be explored and discussed.

EPID 6030 Epidemiological Methods I 3.0

The purpose of this course is to prepare students to function effectively as mid-level epidemiologists in public health agencies or other settings. The knowledge base and skills that are the focus of this course are fundamental to the scope of work expected of master's degree graduates in epidemiology. The course focuses on epidemiologic approaches to activities that are a routine part of public health practice.

MSCR 6450 Molecular Medicine 4.0

This course will provide an opportunity for active participation by the students in analyzing current translational literature and understanding the process by which therapeutic progress is made.

BIOS 6230 or 6240 Computer Package 1.0

Use of statistical packages (6230: SAS; 6240: SPSS) and an introduction to mainframe computing with transmission of data.

MSCR 7150 Seminar/Journal Club 2.0 (1 credit/semester x 2 semesters)

Monthly conference at which students will present and discuss clinical research proposals and published literature.

MSCR 6440 Protocol Design and Writing 3.0

Core course discussing the elements of effective research design, including the basic concepts in clinical trials, the main aspects for different types of trials such as proof of principle stage, Phase I, II, III and IV, and understanding good clinical research methodology. Course will introduce and address issues, idea and outline of design methodology that cover planning, conducting, analyzing, and assessing clinical trials. Concepts and principles of study finance, costing and budgeting will be discussed.

BIOS 6040 Intermediate Biostatistics 3.0

This is a second course in applied biostatistics. It covers one-way and two-way analysis of variance, repeated measures designs, simple and multiple regression and correlation analyses, analysis of covariance, and logistic regression.

GHSD 6030 Principles of Health Systems Administration and Management 3.0

This course presents selected concepts and methods from management practices that are useful in the public health setting. Topics concerning organizational structure, finance, budgeting, human resources, negotiation and others are presented with examples from public health practice.

MSCR 7080 Cultural Competence 3.0

This is an interactive course designed to:

- 1) Introduce general concepts of health disparities, social determinants of health, and cultural competence;
- 2) Apply concepts to real case scenarios through classroom discussions & in the field assignments

MSCR 7300 Pre-surgical Program 27.0

Students will have the opportunity to learn clinical skills essential for a successful transition into residency. The students will develop mentoring relationships with the surgical faculty and will have the opportunity to experience a variety of specialties. The students will participate in the identical simulation training used to teach our surgical residents. The students will begin the clinical skills portion of the program in the first semester with guided study, in order to prepare for the ABSITE (American Board of Surgery In-service Training Exam) in January of their first year. The expectation is for the students to attend core surgical educational conferences through-out the two year curriculum. The clinical research project selected for the MSCR will be in conjunction with the Department of Surgery with the expectation for abstract submission to the annual surgical meeting, the American Clinical Congress, which will occur in the fall of the second year. The sample schedule and course descriptions are outlined in Addendum A.

Requirements:

1. Clinical Research Project with IRB approval during Fall Semester Year 1
2. Take ABSITE Exam at start of Spring Semester Year 1 (and 2 if desired). Independent Study which will include exams from an online question bank.
3. Submit abstract to American College of Surgeons' Clinical Congress in Spring Semester Year 1 (and 2 if desired)
4. OSCE passed during Fall Semester of Year 1
5. Complete FES/FLS certification by graduation
6. Teach ATLS once certified as an Instructor, expected Spring Semester of Year 1
7. Manuscript completion Fall/Early Spring Semester of Year 2
8. Presentation of research at Grand Rounds in Spring Semester of Year 1 and 2

ADDENDUM A

SAMPLE COURSE SCHEDULE

	Year 1 Credits	Year 2 Credits	
<u>SUMMER SEMESTER</u>			
Surgical Education Conferences	1	1	
Clinical Mentorship	2	2	
Residency Didactics	0.5	0.5	
Total	3.5	3.5	
<u>FALL SEMESTER</u>			
Surgical Education Conferences	1	1	
Surgical Research Consortium	0.5	0.5	
Clinical Mentorship	2	2	
Residency Didactics	0.75	0.75	
Bootcamp: Intro to Clinical Skills	0.25		
Advanced Clinical Skills Lab		0.25	
ATLS Certification	0.25		
Pig Lab		0.5	
Total	4.75	5	
<u>SPRING SEMESTER</u>			
Surgical Education Conferences	1	1	
Surgical Research Consortium	0.5	0.5	
Clinical Mentorship	2	2	
Residency Didactics	0.75	0.75	
Bootcamp: Clinical Skills Part II	0.25		
ATLS Instructor Certification	0.5		
FLS/FES	0.75		
Robotics mini-course		0.25	
Total	5.75	4.5	
Overall Total	14	13	27

PRE-SURGICAL PROGRAM COURSE DESCRIPTIONS

Surgical Education Conferences 6.0 (1.0 per semester)

Conferences take place once a week and include 1 hour of Surgical Grand Rounds, 1 hour of Quality & Outcome Review and 30 minutes for Pre-op Case Review. Grand Rounds is a presentation of a relevant surgical topic by a faculty or invited guest (average 1/month) for 40 minutes, followed by a question and answer period. This conference meets CME requirements. Quality & Outcome Review (formerly known as Morbidity & Mortality) is led by the senior residents and involves review of recent cases that met criteria for review. The purpose is to learn about the disease pathophysiology and how it applies to the patient and their treatment plan. Alternative treatments are reviewed. Pre-op Case Review involves presentation of 1 or 2 interesting cases scheduled for the following week. The cases are presented by the resident and the specialties rotate responsibility. Conferences are attended by faculty, residents, and students.

Conference: Friday's 7-9 am

Grade: Pass/Fail

Summary should be emailed to Dr. Zelhart and CC Karen Noble

Surgical Research Consortium 2.0 (0.5 per fall and spring semester)

Weekly surgical research meeting spanning multiple disciplines and occurs once a week. The meeting serves to generate ideas for research, discover possible collaborations, and determine timelines and deliverables to keep the projects moving. Attendees will present the current status of their project on a rotational basis.

Conference: Friday's 9-10 am

Grade: Pass/Fail

Clinical Mentorships 12.0 (2.0 per semester)

Students are paired with surgeons of different specialties for 4 month blocks. The student would observe ½ day clinic per week ensuring no overlap with Tulane medical students. Currently many clinics are not attended by students. Student would observe rounds once per week and one operation per month. The ultimate goal of these mentorships is to increase exposure to a variety of specialties and foster a mentor relationship in order to advocate for the student when applying for residency.

Conference: Friday's 9-10 am

Grade: Pass/Fail from Mentor

Residency Didactics 4.0 (0.5 per summer semester, 0.75 per fall and spring semester)

Resident didactics occur weekly to cover a variety of subjects in order to prepare for the surgical in-service exam. Students will prepare the same material and observe the lecture. Role is observership only so not to interfere with General Surgery Residents.

Lecture: Tuesdays 5:00-6:30 pm

Independent Study 0.0 credits (not listed)

Students will prepare for the ABSITE by independent reading and completion of subject-based tests through our subscription question bank.

Skills 3.0

1. Bootcamp: Intro to Clinical Skills, Clinical Skills Part II and Advanced Clinical Training
 - a. Each is an 8+ hour, interactive seminar in our simulation center. The student will progressively learn practical skills that will prepare them to be a successful intern and resident.
2. ATLS
 - a. Each student will become ATLS certified and continue with training to become an Instructor. Once a Certified Instructor, the student will teach in the ATLS classes going forward.

3. FLS/FES
 - a. Each student will experience and pass the same courses expected of our residents in the Fundamentals of Laparoscopic Surgery and Endoscopy.
4. Pig Lab
 - a. Each student will participate in a 1-2 day pig lab and follow the same agenda for performing operations as is required in our Honor's Surgery Elective.
5. Robotics mini-course
 - a. Each student will complete the mini-course taught by our minimally invasive faculty.