

Masters of Science in Clinical Research (MSCR) Curriculum

Goal/Objective of the MSCR

The MSCR program is an interdisciplinary research degree program housed within the Department of Epidemiology in the School of Public Health. The program is designed to develop the skills necessary for a successful career as a principal investigator and collaborator in clinical research. The program will emphasize:

- 1) Study design
- 2) Fundamentals of data analysis and collaboration with methodologists, including biostatisticians
- 3) Proposal development/grant writing
- 4) Interdisciplinary collaboration
- 5) Project oversight and management, including patient safety and IRB compliance
- 6) Oral and written presentation of study results
- 7) Professional development

Students

The program is designed for persons planning a career as a clinical or translational investigator who will assume leadership roles in research projects and research teams. Applicants must have completed training in a primary substantive research or clinical area. The MSCR is intended to complement the substantive training in these primary substantive areas. **Applicants must have a doctoral level professional degree (M.D., Pharm.D., Ph.D., D.D.S., nurses with Ph.D., D.V.M. etc.) or extensive health professions experience (R.N.'s, P.A's). At the time of enrollment in the MSCR, participants will simultaneously be residents, clinical fellows, post-doctoral fellows, or junior faculty at UNC or Duke University.** We anticipate that each student will already be affiliated with a "home academic program", reflecting either the funding source (e.g. T32 or K12 funding), training program (e.g. post-doctoral fellowship) or department. The program will be limited to 24 students per year.

Description of the Program

The program is designed to be completed over 2 academic years. The program requires a minimum of 36 credit hours and is consistent with requirements in the Department of Epidemiology. Students must be registered for classes in a minimum of three semesters.

The program is intended for a broad range of clinical and translational researchers. Core courses in the curriculum will address issues pertinent to all areas of clinical and translational research. To accommodate the special needs of different areas in clinical and translational research, participants will select one of three tracks:

- 1) Translational ("Bench to Bedside") – Persons with experience in basic science who are intending to continue work that will have a strong component of basic science
- 2) Clinical Trials – Persons with a specific career interest in the conduct of traditional clinical trials
- 3) Health Services/Population Studies – Persons with primary interest in health services and population studies, including health services interventions, observational studies, medical decision-making, health behavior and pharmacoepidemiology

The program will rely heavily on experiential learning, in addition to didactic sessions. Assignments in the core courses will be geared toward practical study-related issues. Whenever possible, large classes will include small group sessions to provide greater opportunity for faculty interaction.

The core and track related courses, in combination with a Masters Paper, will provide nearly all of the course credit hours required for the degree (minimum 32 credit hours, maximum 38). Some students will need a minimum of 4 elective credit hours to complete the degree requirements. These elective credits may be selected from any course relevant to the student's career goals and must be approved by the student's advisor.

Manuscripts and grants are the "currency" of clinical research. Consequently, the program will require two significant products. A Masters Paper will be required of all students. The paper will be original work in the form of primary data collection and analysis, secondary data analysis, or systematic review (or meta-analysis) of previously conducted studies. The Masters Paper will be supervised by the student's mentor with an appropriate second reader. Content of Masters Papers will be approved by the core faculty of the program. The Master's Paper should be submitted for publication (or to an external review committee in cases of multicenter studies) prior to completion of the degree.

In addition to the Masters Paper, students will be expected to complete a grant proposal targeted to an NIH or foundation funding source. The proposal may be for a career development award or an investigator-initiated research grant. The research proposal will be developed within the context of EPID 805/806.

Clinical and translational research is conducted in multidisciplinary, collaborative teams. The program is designed to give these future investigators the skills to succeed in the current environment of clinical and translational research. Collaboration will be fostered through formal and informal group exercises, peer review of colleagues' work, and group discussions of ongoing research. Participants will develop the skills to design sophisticated clinical and translational research studies, in combination with the skills to conduct and lead the research projects.

Mentors and Advisors

We expect all participants in the MSCR to have mentorship in their home departments or training programs. At least one mentor/advisor must have experience in clinical research. We will involve the mentors directly in the student's training, within coursework and the Master's Paper. For example, in the EPID 805/806 sequence, mentors will be expected to give meaningful feedback on the proposals as they are being developed, along with the advice and guidance of the course faculty. A clear mentor relationship will be a requirement for enrollment in EPID 805/806.

Core Courses

Course #	Course Name	Cred	S	Description/Content
<i>Study Design and Analysis</i>				
EPID 711	Clinical Measurement & Evaluation	3	F	Epidemiological and Clinical Measures; Study Design; Bias and Confounding; Diagnostic Tests
PUBH 741 (BIOS 541)	Quantitative Methods for Health Care Professionals	4	F	Concepts of statistical testing, tests for continuous variables, tests for categorical variables, linear regression, logistic regression, and survival analysis
EPID 690 ¹	Design of Clinical Research (<i>new course</i>)	3	S	Pilot and Exploratory Studies; Surveys; Case Control; Cohort; Clinical Trials; Experimental Clinical Studies; Medical Decision Making; Administrative Database Secondary Analyses
PUBH 742 ² (BIOS 542)	Quantitative Methods for Health Care Professionals Required hours = 14	4	S	Application of regression techniques in clinical research.
<i>Proposal development/Grant writing; Project Oversight and Management</i>				
EPID 805	Clinical Epidemiology and Clinical Research Methods	4	F	Grantwriting/Proposal Development; Project Implementation and Oversight; Critique of Grant Proposals
EPID 806	Clinical Research Skills	4	S	Grantwriting/Proposal Development; Project Implementation and Oversight; Critique of Grant Proposals
Required hours = 8				
<i>Professional Development; Oral and Written Presentation of Study Results</i>				
EPID 896 ³	Seminar in Clinical Research (K30 Seminar)	1	F	Professional Development; Writing and Presentation Skills; Major emphasis is given to developing the professional skills needed to succeed in academic medicine, including manuscript preparation, working in teams, negotiation, navigating NIH, etc. Course includes both large group discussions, often with a panel of local experts, and small group discussions of participants own work.
EPID 896	Seminar in Clinical Research (K30 Seminar)	1	S	Professional Development; Writing and Presentation Skills (as above)
EPID 992	Masters Paper	3-6		Preparation of master's paper in manuscript format. Ideal is paper for publication.
Required hours = 5-8				

¹New course offered for first time Spring 2009

²Course is strongly recommended, but not required. Course is required for persons in either Clinical Trials or Health Services/Population tracks

³Participation for two academic years in EPID 896 is required. Persons may take EPID 896 for one year under exceptional circumstances with permission of their advisor and approval of the Program Director.

Track Specific Courses

Course #	Course Name	Cred	S	Description/Content
<i>Translational Track – At least two of the following or approved alternative</i>				
EPID XXX	Study Design and Analysis for Translational Researchers <i>(new course, not yet available)</i>	3	F	Design and analytical issues specific for those with a basic science background wishing to bridge to clinical studies
EPID 743	Genetic Epidemiology: Methods And Applications	3	F/S	Concepts and methods of genetic epidemiology, including segregation analysis, linkage analysis, and gene-environment interaction. Includes whole genome approaches
EPID 690	Biomarkers in Population Research	2	F	Collection and analysis of biospecimens with incorporation into epidemiological, biomedical, and social science frameworks
DPET 855	Principles of Pharmacokinetics	3	F	Pharmacokinetic theory, mathematical model development
DPET 832	Pharmacogenomics	2	S	Applications of pharmacogenomics to development of new medications
ENVR 442	Biochemical and Molecular Toxicology	3	S	Biochemical and molecular actions of toxicants and assessment of cellular and molecular effects
EPID 733	Clinical Trials in Epidemiology	3	S	Design, implementation and analysis of clinical trials
PATH 723	Translational Pathology & Laboratory Medicine	2	S	Translating basic science into clinically applicable diagnostics and therapies to improve human disease outcomes
PATH 725	Cancer Pathobiology	3	S	An interdisciplinary approach draws from epidemiology, genetics, molecular biology, and clinical medicine to investigate cancer etiology, pathogenesis, prevention, and treatment
PSYC 701	Biological Basis of Behavior I	3	F	Biological basis of behavior with an emphasis on pain mechanisms
<i>Clinical Trials Track – At least two of the following or approved alternative</i>				
EPID 733	Clinical Trials in Epidemiology	3	S	Design, implementation and analysis of clinical trials
EPID 690	Quantitative Evaluation of Public Health Interventions	2	F	Methods for evaluating the effects of public health interventions with focus on infectious disease and injury control. Topics include ecologic & time series designs, community-level trials, case-control studies of interventions, and fundamentals of randomized controlled trials.
DPET 830	Development and Clinical Investigations of Drugs	2	F	Preclinical drug safety evaluation, preclinical pharmacology, design of protocols for Phases I-IV, FDA guidelines for clinical study, preparation of study plan, statistics in clinical trials, data analysis,
DPET 833	Experimental Design Considerations in Clinical Research	2	S	Common study designs and their implementation
PUBH 747	Project Management Principles and Practices	3	S	Organizational and management leadership skills from design to implementation of studies
HPM 650	Pharmaceutical Research, Development, and Marketing	3	F	Discovery, development, and marketing of pharmaceuticals
<i>Health Services/Population Track – At least two of the following or approved alternative</i>				
EPID 733	Clinical Trials in Epidemiology	3	S	Design, implementation and analysis of clinical trials

EPID 800	Epidemiology of Medical Care	3		Applications of epidemiological methods and principles to issues of health care organization and delivery
EPID 715	Theory and Quantitative Methods in Epidemiology	5	S	An in-depth treatment of basic concepts and skills in epidemiologic research, including problem conceptualization, study design, research conduct, data analysis and interpretation. Requires EPID 705 as prerequisite, and permission of instructor.
PUBH 747	Project Management Principles and Practices	3	S	Organizational and management leadership skills from design to implementation of studies
PUBH 750	Strategies of Prevention for Clinicians	4	F	Integration of epidemiology and health behavior to prevent disease in the population
EPID 765	Methods and Issues in Pharmacoepidemiology	3	S	Study of the effects and uses of medications in human populations
EPID 690	Biomarkers in Population Research	2	F	Collection and analysis of biospecimens with incorporation into epidemiological, biomedical, and social science frameworks
HBHE 753	Qualitative Evaluation & Research Methods	3	F	Field methods for collecting and analyzing data through observation, interviewing, group methods, and case studies
HPM 496	Seminar in Comparative Effectiveness Research	3	F/S	Readings in comparative effectiveness research. 3 credit option is required
HPM 772	Economic Evaluation of Health Care Technologies; Policy Analysis and Technology Assessment	3	F	Cost-effectiveness, health policy analysis
HPM 766	Cancer Care Quality	3	F	Overuse, underuse, and misuse of care across the cancer care continuum.
HPM 510	Global Perspectives on Ethical Issues in Health Policy and Management	3	S	A comparison of the ethical approaches to health system issues in various countries, such as the different perspectives on informed consent, refusal of treatment, physician-assisted suicide, and reproductive health
HPM 757	Health Reform: Political Dynamics and Policy Dilemmas	3	S	Current trends in the health care system, the dilemmas confronting public and private insurance programs as health care costs increase, options for reform and covering the uninsured, the political history of health reform
NURS 933	Methods for the Evaluation and Improvement of Health Care Systems	3		Health care quality and patient outcomes
DPOP 804	Informatics: Use of Large Health Care Databases	3	F	Analysis of large secondary databases containing patient, physician, or hospital data
DPOP 805	Patient Reported Outcomes: Theory, Methods, Applications	3	S	Theoretical principles of patient-reported outcomes, psychometrics properties, applications of methods
CRP 259	Decision Sciences in Clinical Research	2	F	The use of simulation models of disease natural history, epidemiology, and clinical care as tools for exploring basic scientific questions, study design, clinical decision making, and cost-effectiveness analysis. (Offered at Duke)

Required hours = 4-7

*Students who do not satisfy the 36 credit hour requirement with the core and track-related courses may choose from relevant elective courses approved by their advisors. We anticipate most students requiring additional credit hours will choose 1 or more additional courses in their track.

Typical Schedule (2 year program)

Fall, Year 1 (9-12 credits)

PUBH 741 (BIOS 541) – 4 credit hours
EPID 711 – 3 credit hours
EPID 896 (K30 Seminar) – 1 credit hour
TRACK COURSE (or elective) – 2-4 credit hours

Spring, Year 1 (10-12 credits)

PUBH 742 (BIOS 542) – 4 credit hours
EPID 690 – 3 credit hours
EPID 896 (K30 Seminar) – 1 credit hour
TRACK COURSE – 2-4 credit hours

Fall, Year 2 (7-9 credits)

EPID 805 – 4 credit hours
EPID 896 (K30 Seminar) – 1 credit hour
TRACK COURSE (or elective) – 2-4 credit hours

Spring, Year 2 (10-12 credits)

EPID 806 – 4 credit hours
EPID 896 (K30 Seminar) – 1 credit hour
TRACK COURSE (or elective) – 2-4 credit hours
EPID 992 – Master's Paper (3 credit hours)