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) Clinical research study design: Identify testable research hypotheses; develop appropriate study designs with minimal bias; identify appropriate target populations.
2) Fundamentals of data analysis: Develop appropriate data analysis plans for research hypotheses; implement basic statistical analyses including multivariable regression; understand sample size and power calculations.
3) Grant proposal development: Develop a proposal for clinical/translational research suitable for submission to the National Institutes of Health or research foundation.
4) Interdisciplinary collaboration: Demonstrate knowledge of team science; develop skills for collaboration with research methodologists, including biostatisticians.
5) Project oversight and management: Demonstrate skills to implement a research project, including hiring of appropriate team members, developing and managing budget, overseeing project, ethics approvals, and regulatory reviews.
6) Oral and written presentation: Effectively present research findings orally to peers, lay persons, and the media; Write clearly and succinctly for scientific publication and research proposals.
7) Professional development: Demonstrate knowledge of the academic research environment, sources of research support, and professional advancement. Demonstrate the use of strategies to improve professional effectiveness, such as time management, leadership skills, and management skills.

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 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 four tracks and must complete two courses within a specific track:

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) Comparative Effectiveness Research (CER) – Persons with primary interest in comparisons of the benefits and harms of treatment alternatives (pharmacoepidemiology), diagnostic tests, care delivery models, and/or policies for decision-making using non-experimental or experimental (pragmatic/large simple trials) designs
4) Health Services/Population Studies – Persons with primary interest in health services and population studies, including health services interventions, health behavior and health policy

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 36 course credit hours required for the degree (minimum 34 core/track credit hours). Some students will need a minimum of 2 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 Department of Epidemiology advisor or the Program Director.

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 from their clinical or research program and an advisor in the Department of Epidemiology. Content of Masters Papers will be approved by the core faculty of the program. The Master's Paper is expected to be of publication quality at the time of completion.

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

In addition to the designated advisor in the Department of Epidemiology, we expect all participants in the MSCR to have mentorship in their home departments or training programs (e.g. their clinical department, research department, or other program). 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
Study Design and Analysis (18 hours)				
EPID 711	Clinical Measurement & Evaluation	3	F Y1	Epidemiological and clinical measures; Study design; Bias and confounding; Diagnostic tests
PUBH 741	Quantitative Methods for Health Care Professionals	4	F Y1	Concepts of statistical testing; Tests for continuous variables; Tests for categorical variables; Linear regression; Logistic regression; Survival analysis
EPID 804	Design of Clinical Research	4	S Y1	Pilot and exploratory studies; Surveys; Case control; Cohort; Clinical trials; Large simple/pragmatic trials; Experimental clinical studies; Medical decision making; Administrative database secondary analyses; Exposure and outcome measurement; Quality control
EPID 733	Clinical Trials in Epidemiology	3	S Y1	Design; Implementation and analysis of clinical trials
PUBH 742	Quantitative Methods for Health Care Professionals	4	S Y1	Application of regression techniques in clinical research
Required introduction to Public Health Concepts (3 hours)				
SPHG 600 (alternatives: SPHG 700; PUBH 680)	Introduction to Public Health	3	F/S Y1 or Y2	Introduction to public health including history, key concepts and terms *Approved alternatives:* SPHG 700 and PUBH 680 (both offered online)
Proposal development/Grant writing; Project Oversight and Management (4 hours)				
EPID 805	Clinical Research Skills - III	2	F Y2	Grant writing/proposal development; Project implementation and oversight; Critique of grant proposals
EPID 806	Clinical Research Skills - IV	2	S Y2	Grant writing/proposal development; Project implementation and oversight; Critique of grant proposals
Professional Development; Oral and Written Presentation of Study Results (5-8 hours)				
EPID 802	Clinical Research Skills - I	2	F Y1	Research question development; Abstract/ manuscript writing; Presentations; Reviewing manuscripts; Professional development
EPID 992	Masters Paper	3-6	Y2	Preparation of master's paper in manuscript format. Ideal is paper for publication.

Track Specific Courses

Course #	Course Name	Cred	S	Description/Content
Translational Track – At least two of the following or approved alternative (Minimum 4 credits)				
EPID 742	Biomarkers in Population Research	2	F	Collection and analysis of biospecimens with incorporation into epidemiological, biomedical, and social science frameworks
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 771	Cancer Epidemiology Methods	3	F	Evaluate the strengths and weaknesses of data sources common to cancer survivorship and outcomes studies, focusing on epidemiologic study designs. The course addresses cancer detection, treatment strategies, medical surveillance, and personal behaviors as determinants for prognosis, late effects, and the long-term health of cancer survivors.
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
GNET 742/ GNET 744	Intro to Unix & Perl Programming for Biomedical Researchers & Sequence, Protein Structure and Genome-Wide Data Analysis	1/1	S	Genome databases; sequence retrieval, alignment and analysis, and macromolecular structure retrieval, visualization and analysis; microarrays and next-generation sequencing. Both 742 & 744 must be completed for track credit.
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	Brain & Behavior I	3	F	Biological basis of behavior with an emphasis on pain mechanisms
Clinical Trials Track – At least two of the following or approved alternative (Minimum 4 credits)				
EPID 790	Intervention Epidemiology	2	F	Methods for evaluating interventions with focus on infectious diseases and injury control. Covers 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
HPM 650	Pharmaceutical Research, Development, and Marketing	3	F	Discovery, development, and marketing of pharmaceuticals
PUBH 767	Team Leadership in Research Navigation	3	S	Leadership skills for research

CER/PCT Track – At least two of the following or approved alternative (Minimum 4 credits)

EPID 765	Methods and Issues in Pharmacoepidemiology	3	S	Study of the effects and uses of medications in human populations
EPID 766	Epidemiology Research with Healthcare Databases (with permission of instructor)	3	S	Learn how healthcare utilization data are generated and use databases to identify study populations and conduct epidemiologic analysis of the utilization and comparative effectiveness/safety of prescription drugs and healthcare services. (May require SAS skills)
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)
HPM 496	Seminar in Comparative Effectiveness Research	3	F/S	Readings in comparative effectiveness research. 3 credit option is required
HPM 762	Quality of Care	3	F	This course will review: (1) the current state of the quality of health care in the United States; (2) approaches to assess quality of health care, and (3) strategies that have been implemented or proposed to improve the quality of health care.
HPM 766	Cancer Care Quality	3	F	Overuse, underuse, and misuse of care across the cancer care continuum.
HPM 772	Economic Evaluation of Health Care Technologies; Policy Analysis and Technology Assessment	3	F	Cost-effectiveness, health policy analysis

Health Services/Population Track – At least two of the following or approved alternative (Min 4 credits)

EPID 715 & 716	Theory and Quantitative Methods in Epidemiology	4 & 2	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.
EPID 735	Cardiovascular Disease Epidemiology	3	F	Review of the main causes of cardiovascular disease morbidity and mortality, and their population determinants. Topics include epidemiologic methods, risk factors, strategies for prevention, and a student research project.
EPID 742	Biomarkers in Population Research	2	F	Collection and analysis of biospecimens with incorporation into epidemiological, biomedical, and social science frameworks
EPID 853	Advanced Perinatal and Pediatric Epidemiology	3	S	Methodological issues, including study design and analytic considerations, in the context of

				perinatal and pediatric research
DPOP 803	Social and Behavioral Aspects of Pharmaceutical Use	2	S	This course will draw on medical sociology and health psychology to familiarize students with core theories, research, measures, and design issues relevant to conducting social/behavioral research surrounding pharmaceutical use.
HBEH 715/ PUBH 715	Communication for Health-Related Decision Making	2	S	Foundation and skills to understand and improve decision making that affects people's health, including theoretical basis
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 620	Implementing Health Informatics Initiatives	3	S	Implementation of informatics programs and projects in health organizations to facilitate information use for quality or efficiency improvement
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
HPM 762	Quality of Care	3	F	This course will review: (1) the current state of the quality of health care in the United States; (2) approaches to assess quality of health care, and (3) strategies that have been implemented or proposed to improve the quality of health care.
HPM 765; EPID 772	Cancer Prevention & Control	3	F	An interdisciplinary overview of cancer prevention and control. Emphasis on projects and activities from perspectives of epidemiology, health behavior and education, and Health Policy and Management.
HPM 766	Cancer Care Quality	3	F	Overuse, underuse, and misuse of care across the cancer care continuum.
HPM 767	Disseminating Evidence and Innovation in Cancer Care	3	S	Concepts, theories, and methods of disseminating and implementing evidence-based interventions to improve quality in cancer care; Methods for conducting rigorous research on dissemination and implementation.
HPM 772	Economic Evaluation of Health Care Technologies; Policy Analysis and Technology Assessment	3	F	Cost-effectiveness, health policy analysis
PUBH 711	Critical Issues in Global Health	3	F	Examines complex tapestry of social, economic, political, and environmental factors that affect global health;
PUBH 712	Global Health Ethics	3	S	Theoretical and practical aspects of public health ethics. Develop students analytical skills to evaluate ethical issues related to public health policy, prevention, treatment, and research
PUBH 714	Monitoring and Evaluation of Global Health Programs	3	Su	Basic concepts and practices in M&E;formative research, stakeholder engagement, conceptual frameworks, data collection methods, indicator development, survey and focus group design,

				performance monitoring and designs for outcomes, impacts and efficiency
PUBH 767	Team Leadership in Research Navigation	3	S	Team leadership and management principles and practices with an emphasis on successful team leadership in clinical research
PUBH 750	Strategies of Prevention for Clinicians	4	F	Integration of epidemiology and health behavior to prevent disease in the population

Required hours = 4-6

*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 (12 credits)
PUBH 741 (BIOS) – 4 credit hours
EPID 711 – 3 credit hours
EPID 802 – 2 credit hours
SPHG 600 (Required public health course; or SPHG 700 or PUBH 680) – 3 credit hours

Spring, Year 1 (13-15 credits)
PUBH 742 (BIOS) – 4 credit hours
EPID 733 – 3 credit hours
EPID 804 –4 credit hours
TRACK COURSE – 2-4 credit hours

Fall, Year 2 (4-6 credits)
EPID 805 – 2 credit hours
TRACK COURSE (or elective) – 2-4 credit hours

Spring, Year 2 (7-9 credits)
EPID 806 – 2 credit hours
TRACK COURSE (or elective) – 2-4 credit hours
EPID 992 – Master's Paper (3 credit hours)

Alternate Schedule (2 year program- Summer start)
Summer, Year 1 (4 credits)
PUBH 741 (BIOS) – 4 credit hours

Fall, Year 1 (8 credits)
EPID 711 – 3 credit hours
EPID 802 – 2 credit hours
SPHG 600 (Required public health course; or SPHG 700 or PUBH 680) – 3 credit hours

Spring, Year 1 (13-15 credits)
PUBH 742 (BIOS) – 4 credit hours
EPID 733 – 3 credit hours
EPID 804 –4 credit hours
TRACK COURSE – 2-4 credit hours

Fall, Year 2 (4-6 credits)
EPID 805 – 2 credit hours
TRACK COURSE (or elective) – 2-4 credit hours

Spring, Year 2 (7-9 credits)
EPID 806 – 2 credit hours
TRACK COURSE (or elective) – 2-4 credit hours
EPID 992 – Master's Paper (3 credit hours)