Master of Science in Clinical, Biomedical, and Translational Investigations

The Masters of Science in Clinical, Biomedical, and Translational Investigations (CBTI) is a joint effort to train medical students, fellows, or other health professionals, including faculty and other scientists conducting clinical related research, in clinical research methods to translate clinical, biomedical and technological discoveries into advances in population-based, clinical or basic science research. The MS Program of Clinical, Biomedical, and Translational Investigations (CBTI) is available to medical students who have completed their second year of medical school, and pre-doctoral students who are interested in expanding their pre-doctoral training to include methodology associated with conducting translational research. Pre-doctoral students will earn a joint degree (PhD in their research area and an MS in CBTI). In addition, the MS CBTI Program is tailored to MD's doing fellowships at USC or Children's Hospital Los Angeles (CHLA), faculty interested in expanding their research careers, or are recipients of Young Investigator Awards, including Southern California Clinical Translational Science Institute's (SC CTSI) Center for Education, Training, and Career Development K and T Awardees. Tracks include: 1) Clinical Translational Research, , 2)Community-based Intervention Trials, 3) Design, Conduct and Analysis of Clinical Studies, .4) Epidemiology and Disease Etiology, 5) Health Outcomes Research, 6) Environmental Epidemiology, 7) Molecular Biology, 8) Cell Biology, 9) Vision Science, and 10) Alternative Track Option.

The MS program in Clinical, Biomedical, and Translational Investigations is designed to train students, fellows and faculty for future independent research careers in an academic, government or private sector setting. The objective of the MS program is to produce a clinical researcher with either an in-depth knowledge in laboratory methodologies or statistical and analytic skills in population-based, clinical studies or outcomes research. The program gives students a solid background in the methodological aspects of translational research, and in statistical thinking as applied to molecular epidemiology, as well as a solid grounding in biostatistical, epidemiological methods, and community based intervention strategies.

Program Co-Directors

Stanley P. Azen, Ph.D., Professor, Co-Director of Biostatistics, Preventive Medicine, Co-Director CETCD Michael L. Paine, B.Sc., B.D.S., Ph.D., Associate Professor, Director, Graduate Program in Craniofacial Biology

Administration

MS in Clinical and Biomedical Investigations, KAM 200, mc 9023 EMAIL: <u>msclnbio@usc.edu</u>, Phone: 323-442-2965

Admission Requirements

Applicants must apply to the Graduate School and meet the minimum requirements for admission to the Graduate School. The Departments of Preventive Medicine, Cell and Neurobiology, Family Medicine and the Center for Education, Training and Career Development (CETCD) jointly administer the program.

The Program will consider applicants who satisfy all requirements for admission to the Graduate School. For the MS program in Clinical and Biomedical Investigations, MCAT scores may be substituted for the GREs. Applicants not meeting Graduate School requirements for regular standing may, with approval of the Graduate School, be conditionally admitted. Regular standing is contingent upon maintaining a GPA of 3.0 in the first 12 units of graduate studies. All graduate students must maintain a GPA of 3.0 throughout their graduate studies.

General Requirements

Graduation requires the completion of a minimum of 29 units, of which a minimum of 15 units are didactic course credits taken in the first year (including summer sessions), with the remaining units being directed to: a) PM 590 (directed research, 1-12 units) and PM 594ab (thesis, 4 units) taken in the second year. The equivalent of one year of full-time effort must be devoted to research leading to a master's thesis. The thesis provides a structure for the development of a plan to address a research problem and a suitable approach to the analysis and presentation of the results.

Because the background and interests of applicants varies widely, one of the Co-Directors will consult with each student prior to the first year in order to design an individualized schedule of recommended courses, or this may be negotiated with a student's faculty sponsor. At the end of the first year, the trainee must submit a final program plan to the Co-Directors. This will summarize the courses taken, the proposed thesis title, and the names and credentials of the MS Thesis Committee. One of the members of the MS Thesis Committee will be the trainee's research advisor and will serve as the Chair of the committee. At least one member of the Thesis Committee must be from outside the student's department. For faculty, at least two members of the Thesis Committee must be from outside the student's department.

For those trainees or SC CTIS'S CETCD K and T awardees who do not wish to pursue a MS degree, the school offers a Certificate in Clinical, Biomedical, and Translational Investigations (CBTI) The certificate program requires completion of 12 credits, and a minimum of 6 months of practical research experience working on a research project (PM590) approved by either an Oversight Committee or the CETCD'S K and T Award Committee Review Process.

Students are expected to attend the three day Workshop on NIH Proposal Development offered by Thomas Ogden MD, PhD, and a Workshop on the principles of Scientific Manuscript Preparation.

Certificate Program

Students who do not wish to pursue an M.S. degree may earn a university Certificate in Clinical, Biomedical, and Translational Investigations. The certificate program requires 12 credits and a minimum of six months of practical experience working on a research project approved by the student's mentor and the program's Co-Directors.

CLINICAL TRANSLATIONAL RESEARCH

(13-16 UNITS)

PM 510	Principles of Biostatistics	4
PM 512	Principles of Epidemiology	4
PM 523	Design of Clinical Studies	3
OR		
PM 612a	Clinical Translational Research 1	4
PM 612b	Clinical Translational Research 2	4
PM 612c	Clinical Translational Research 3	4
Electives (pick one course)		
BIOC 543	Human Molecular Genetics	4
MPTX 511	Introduction to Medical Product Regulation	3
MPTX 602	Science, Research, and Ethics	2
PM 511b	Data Analysis	4
PM 570	Statistical Methods in Human Genetics	4
PM 518a	Statistical Methods for Epidemiological	3
	Studies	
RSCI 530	Translational Medicine: An Overview	2
COMMUNITY-BASED INTERVENTION TRIALS		(16 UNITS)
DN/ 512	Principles of Epidemiology	Λ
DM 528	Program Design and Evaluation	т Л
PM 563	Organizing and Mobilizing Communities	
1101 303	for Global Health	т
Electives (pick one course)		
PM 526	Communications in Public Health	4
PM 562	Intervention Approaches for Health	4
	Promotion and Disease Prevention	
DESIGN, CONDUCT AND ANALYSIS OF CLINICAL STUDIES		(18 UNITS)
PM 510L	Principles of Biostatistics	4
PM 511a	Data Analysis	4
PM 523	Design of Clinical Studies	3
PM 538	Introduction to Biomedical Informatics	3
PM 570	Statistical Methods in Human Genetics	4
EPIDEMIOLOGY AND DISEASE ETIOLOGY		(14-15 UNITS)
		A
	Principles of Biostatistics	4
	Principles of Epidemiology	4
PIVI 517a	Research Methods in Epidemiology	3

Electives (Pick one course)		
PM-518a	Statistical Methods for Epidemiological Studies I	3
PM 527	Epidemiology of Infectious Disease	4
PM 529	Environmental and Occupational Health:	
	An Epidemiological Approach, or	
PM 533	Genetic and Molecular Epidemiology	3
HEALTH OUTCOMES RESEARCH		(16 UNITS)
PM 511a	Data Analysis	4
PMEP 538	Pharmaceutical Economics	4
PMEP 539	Economic Assessment of Medical Care	4
PMEP 540ab	Seminar in Pharmaceutical Economics and Policy	2-2
ENVIRONMENTAL EPIDEMIOL	OGY	(17-18 UNITS)
PM 510	Principles of Biostatistics	4
PM 512	Principles of Epidemiology	4
PM 518a	Statistical Methods for Epidemiological	3
	Studies I	
PM 529	Environmental Health	3
Electives (pick one course)		
PM 511a	Data Analysis I	4
PM 533	Genetic and Molecular Epidemiology	3
PM 570	Statistical Methods in Human Genetics	4
PM 599	Geographic Information Systems for	4
	Environmental and Health Analysis	
MOLECULAR BIOLOGY		(16 UNITS)
	Coll Biology	Λ
INTD 561	Molecular Constics	4
	Rischemictry	4
	воспетніхну	4
Flectives (Pick one course)		
BIOC 543	Human Molecular Genetics, or	
INTD 504	Molecular Biology of Cancer, or	
INTD 555	Biochemical and Molecular Bases of Disease or	
MICB 551	Procenyotic Molecular Genetics	Λ
NICE 551	riocal your molecular denetics	4
CELL BIOLOGY		(15 UNITS)
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INTD 531	Cell Biology	4
INTD 571	Biochemistry	4
PATH 553	Methods in Cellular and Clinical Pathology	3

Electives (Pick one course)		
INTD 504 INTD 555	Molecular Biology of Cancer, or Biochemical and Molecular Bases of Disease	4 4
INTD 501	Recent Advances in Vision Science	1. max 4
INTD 531	Cell Biology	4
INTD 571	Biochemistry	4
INTD 573	Systems Physiology and Disease II -	4
PSCI 667	Intracellular Drug Delivery and Targeting	2
ALTERNATIVE OPTIONS TRA	ACK	(MINIMUM 15 UNITS)

Courses are determined by mentor and student, based on research interests, with approval from the Co-Directors of the program.

Seminars/Workshops

Participation is required in a Recent Advances Journal Club to learn how to read papers critically and develop the speaking skills necessary to explain a research paper. Faculty members in the program rotate as course directors in order to emphasize new topics. Students are expected to attend the three-day workshop on NIH Proposal Development offered by Thomas Ogden, Ph.D., and a workshop on the principles of scientific manuscript preparation.

COURSE DESCRIPTIONS

PM 510L Principles of Biostatistics (4: 2 lec, 2 lab; Fa, Sp, Sum)

Nature, scope, and terminology of biostatistics; appropriate uses and common misuses of health statistics; practice in the application of selected statistical procedures; introduction to statistical software (EXCEL, SPSS, nQuery).

PM 511aL Data Analysis (a: 4, Fa, Sp)

Major parametric and nonparametric statistical tools used in biomedical research, computer packages including SAS. Includes laboratory. Prerequisite: 510L or the equivalent.

PM 511bL Data Analysis (b: 4, Sp)

Exploratory data analysis, detection of outliers, fitting data with linear and nonlinear regression models, computer packages including S-PLUS and SPSS. Includes laboratory. Prerequisite: 510L or the equivalent.

PM 512 Principles of Epidemiology (4, Fa, Sp)

Terminology and uses of epidemiology and demography; sources and uses of population data; types of epidemiologic studies; risk assessment; common sources of bias in population studies; principles of screening.

PM 517a Research Methods in Epidemiology (a: 3, Fa)

Study design, ascertainment of study subjects, questionnaire development, various methodological issues in data analysis and interpretation including bias, measurement error, confounding and effect modification. Prerequisite: PM510L; PM511aL; PM512; and PM518a.

PM 518a Statistical Methods for Epidemiological Studies I (3, Sp)

Principles and methods used in epidemiology for comparing disease frequencies between groups. Restricted to the analysis of binary outcome variables. Prerequisite: PM 512.

PM 523 Design of Clinical Studies (3, Sp)

Design, conduct, and interpretation of results of clinical trials. Emphasis on principles affecting structure, size, duration of a trial, and the impact of ethical and practical considerations. Prerequisite: PM510L or equivalent.

PM 526 Communications in Public Health (4, Sp)

Application of communication theories and methods to community health problems. Includes background assessment, program design, evaluation, social marketing, media advocacy, review of major health campaigns. Recommended preparation: PM 500.

PM 527 Epidemiology of Infectious Disease (3, Fa/Sp)

Survey of natural history of infectious disease, methods of disease control and outbreak investigation. Prerequisite: PM512 or consent of the instructor.

PM 528 Program Design and Evaluation (4, Sp)

Core concepts, methods and values of public health program planning and evaluation, including community needs assessment, writing objectives, designing health promotion programs, process and outcome evaluation. Recommended preparation: PM 500.

PM 529 Environmental Health (3, Sp)

An overview of environmental health, identifying issues and assessing effects of exposure on health and potential interventions for reducing adverse health risk. Prerequisite: PM510, PM512 or equivalent.

PM 533 Genetic and Molecular Epidemiology (3, Fa)

Genetic principles; design and analysis of family studies; introduction to likelihood estimation; segregation and linkage analysis; biomarkers of exposure, susceptibility, and disease; laboratory methods; susceptibility genes; association and linkage disequilibrium. Prerequisites: PM510, 511a, 512, 518a.

PM 538 Introduction to Biomedical Informatics (3, Sum) An overview of current topics, enabling technologies, research initiatives, and practical considerations in Biomedical Informatics.

PM 562 Intervention Approaches for Health Promotion and Disease Prevention (4, Sp) An in-depth review of approaches to health promotion and disease prevention intervention in different settings, using varied strategies, and for different target groups.

PM 563 Organizing and Mobilizing Communities for Global Health (4, Fa) Theories, principles, models, techniques, dynamics and effective strategies of organizing and mobilizing communities for global public health.

PM 570 Statistical Methods in Human Genetics (3, Sp)

An introductory course in the statistical methods used in the analysis of human genetic data. Prerequisites: PM510, 511a, 512.

PM 590 Directed Research (1-12)

Research leading to the master's degree. Maximum units which may be applied to the degree to be determined by the department. Graded CR/NC.

PM 599 Special Topics (2-4, max 8)

Special topics relevant to the study of selected issues and areas of health behavior research or other aspects of preventive medicine.

PM 612a – Clinical Translational Research 1 (4)

First of three courses in Clinical Translational Research, a discipline that fosters the multidirectional integration of basic research, patient-oriented research, and population-based research, with the long-term goal of improving the health of the public. Students are introduced to the fundamental processes that drive scientific knowledge across the clinical translational spectrum.

PM 612b - Clinical Translational Research 2 (4)

Second course in the methods of clinical translational research, a discipline that fosters the multidirectional integration of basic research, patient-oriented research, and population-based research, with the long-term goal of improving the health of the public. This course focuses on

developing competency in the analysis of data and the interpretation of results. It expands on and reinforces the foundational research and team science skills developed during Clinical Translational Research Methodology I (CTR1 Prerequisites: PM 612a

PM 612c – Clinical Translational Research 3 (4)

Course builds on core competencies attained in Clinical Translational 1 and 2 by providing an opportunity for an integrative "capstone" experience. Students continue to refine their methodological foundation, apply team science approaches, and develop scientific writing skills Prerequisites: PM 612a and 612b

BIOC 543 Human Molecular Genetics (4)

Comprehensive course covering basic principles of human genetics, genetic disease, the Human Genome Project, and gene therapy. Recommendation preparation: undergraduate genetics.

INTD 501 Recent Advances in Vision Science (1 unit, max 4)

Recent advances in the understanding of the ocular surface are reported and discussed; students will learn how to read papers critically, develop speaking skills to explain a research paper and attend a three-day workshop on NIH proposal development and scientific manuscript preparation. Graded CR/NC.

INTD 504 Molecular Biology of Cancer (4)

Epidemiology, pathobiology, carcinogenesis, tumor biology and heterogenetity; retroviruses, oncogenes, cell cycle control, genetics of cancer, tumor immunology; treatment strategies. Prerequisite: MICB 501.

INTD 531 Cell Biology (4)

Current perspectives on major research areas in cell biology. Emphasis will be on in-depth examination of cellular structures, regulatory processes, intracellular routing and targeting, and cell/environmental interactions.

INTD 555 Biochemical and Molecular Basis of Disease (4)

Biochemical and molecular abnormalities in disease states; interdepartmental with Department of Pathology. Prerequisite: general biochemistry

INTD 561 Molecular Genetics (4)

Prokaryotic and eukaryotic molecular genetics: DNA and RNA structure and function; biochemistry and molecular biology of replication, transcription, RNA processing, translation, and regulation of gene expression. Emphasis is on eukaryotic organisms with comparisons to prokaryotes. Prerequisite: INTD 571.

INTD 571 Biochemistry (4, Sp)

Physical-chemical basis of life processes: protein structure and enzyme function; synthesis and metabolism of carbohydrates, lipids, amino acids, and nucleotides. (Duplicates credit in former BIOC 441.) Prerequisite: open to qualified students.

INTD 573 Systems Physiology and Disease II (4, Sp)

Mammalian organ systems operation during health, and pathophysiologic analysis of related diseases with focus on neuroscience, immunology, metabolism, endocrine, reproduction, GI and liver. Faculty from basic and clinical sciences. Open to graduate students in biomedical science only. Recommended preparation: undergraduate degree in a biological science. *Corequisite:* INTD-531

MICB 551 Procaryotic Molecular Genetics (4, Fa)

Macromolecular processes and their regulation in procaryotics; DNA replication, transcription, and post-transcriptional events in general and as related to operons, phage biology, and eucaryotic organelles.

MPTX 511 Introduction to Medical Product Regulation (3, Fa, Sp, Sum) Introduction to regulatory environments surrounding medical product development, manufacturing and marketing; operation of federal, state and international regulatory bodies. Recommended preparation: undergraduate degree in pharmacy, medical or independent health sciences, engineering or equivalent mix of post-secondary training and industry medical or independent health sciences, engineering or equivalent mix of post-secondary training and industry experience.

MPTX 517 Structure and Management of Clinical Research (4, Sp) Development and execution of clinical trials: bioethical principles, good clinical practices, project management and documentation.

MPTX 602 Science, Research and Ethics (2, Fa) A discussion of the unique technological and philosophical issues that challenge modern scientists and a discernment of ethical responses to those challenges.

PATH 553 Methods in Cellular and Clinical Pathology (a: 3, Fa) Includes advanced techniques in: a: cell biology and protein chemistry; b: DNA analysis. The course is a practical approach to acquaint graduate students with current methodologies and applications used in biomedical research.

PMEP 538 Pharmaceutical Economics (4, Sm) Introduction to pharmacoeconomics with special emphasis on the role of pharmaceuticals and the pharmaceutical industry, insurance, managed care, regulation and pricing. Prerequisite: ECON 500.

PMEP 539 Economic Assessment of Medical Care (4, Fa) Principles of cost-benefit analysis and medical cost-effectiveness analysis with applications in medical care and the pharmaceutical field. Prerequisite: ECON 500 and ECON 581.

PMEP 540ab Seminar in Pharmaceutical Economics and Policy (2-2, Fa) This seminar will expand the student's understanding of fundamental techniques used in analyzing pharmaceutical policies and programs. Prerequisite: a: PMEP 538 and PMEP 539; b: PMEP 540a.

PSCI 667 Intracellular Drug Delivery and Targeting (2, Sp) Principles of cost-benefit analysis and medical cost-effectiveness analysis with applications in medical care and the pharmaceutical field. Prerequisite: ECON 500 and ECON 581.

RSCI 530 Translational Medicine (2, Fa)

An overview of principles and concepts underlying drug discovery and development, including terminology of translational science. Recommended preparation: undergraduate degree in pharmacy, medical or independent health sciences, engineering or equivalent mix of post secondary training and industry experience; enrollment in M.S., Regulatory Science, Certificate in Preclinical Drug Development.