

CLINICAL AND TRANSLATIONAL SCIENCE
GRADUATE PROGRAM

ACADEMIC YEAR 2010-2011

CLINICAL AND TRANSLATIONAL SCIENCE GRADUATE PROGRAM

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PREFACE

The Renewal of the Clinical Research Enterprise: Context for the Tufts University Sackler School of Graduate Biomedical Sciences Clinical and Translational Science Graduate Program

In 1999, responding to the clear need for renewal of clinical research training and to the NIH-led call for the development of rigorous training in clinical research disciplines, the Clinical Research Graduate Program of the Tufts University Sackler School of Graduate Biomedical Sciences became the nation's first MS/PhD program in clinical research in a biomedical graduate school.

A decade after the initiation of the Sackler School Clinical Research Program, Tufts University was awarded an NIH Clinical and Translational Science Award. This allowed creation of Tufts Clinical and Translational Science Institute (CTSI), aimed at taking the fullest possible advantage of the extraordinary array of disciplines, novel methods, and opportunities across Tufts University and its affiliates, to generate innovative and impactful research. Education and career development were understood to have a central role in supporting the mission of the CTSI, and Tufts CTSI was created with the Sackler Clinical Research Program as a central resource. The CTSI leadership realized that in their objective to transform research across Tufts University and its affiliates and partners, it had to clearly reflect the core philosophy, content, and processes in its research education and training programs. The educational programs had to reflect the commitment to full-spectrum translational research objectives—from bench to bedside to practice, to public benefit and policy—and back again, across each translational step. Two changes were made in the Graduate Program to better meet this challenge, and to optimally leverage its world class faculty and research programs. First, it changed its name from “Clinical Research Program” to “Clinical and Translational Science Program,” to match the emphasis of Tufts CTSI in which it resides. Second, it consolidated what had been six degree Concentrations into three: *Evidence-based Clinical Effectiveness Research; Clinical Investigation; and Health Services and Outcomes Research*. Additionally, reflecting the desire to promote interdisciplinary research education, the option was provided to allow for students to have a focus in another Tufts School or discipline from which some elective courses could be selected within their Concentration. Also, when appropriate, joint programs with other Tufts Schools are encouraged.

Together, the name change, emphasis on the full spectrum of translational research in the concentrations, and the facilitation of interdisciplinary education, all reflect the CTSI approach. Thus, the Graduate Program continues to reflect the core values, mission, and methods of Tufts CTSI, and continues to support training and career development of translational researchers.

Harry P. Selker, MD, MSPH
Program Director
Dean, Tufts CTSI

OVERVIEW

The Tufts University Sackler School of Graduate Biomedical Sciences Clinical and Translational Science Graduate Program leads to an MS or PhD, typically done as part of a two or more year postdoctoral fellowship for clinicians or for junior faculty. The MS usually takes two years to complete, the PhD twice that. The majority of students are postdoctoral fellows or faculty at Tufts Medical Center and other Tufts-affiliated hospitals, but others come from other local institutions and industry.

The Clinical and Translational Science Graduate Program is primarily directed at individuals already trained in the medical sciences, primarily fully-trained physicians, but also for others with analogous backgrounds (e.g., DDS, DVM) who want further training for research careers. Most students elect to do an MS; others a full PhD.

Students take core courses essential to developing the necessary competencies to become independent researchers and leaders in their fields of research, including principles and methods of epidemiology and study design and conduct, writing, and biostatistics. Students also elect a concentration to develop a greater depth of knowledge and skills in a selected area. In addition to selecting a thesis relevant to that Concentration, students work with the Concentration Leader to identify electives and/or projects to develop the competencies for that area.

Students in the Clinical and Translational Science Graduate Program may elect one of three **Concentrations**:

Evidence-based Clinical Effectiveness Research

This Concentration includes the areas known as Comparative Effectiveness Research (CER), Evidence Based Medicine (EBM), and related areas that advance the translation of information about the effectiveness of treatments and healthcare strategies into practice.

Clinical Investigation

This Concentration is intended for clinician-investigators desiring methodologic grounding for the full range of patient-oriented clinical research including randomized controlled trials, and Phase I, II, and III trials.

Health Services and Outcomes Research

This Concentration emphasizes application of a variety of methods to the investigation of population health improvement and the organization, delivery, financing, and outcomes of health care services.

In addition to selecting a Concentration, students may select another typically clinical discipline for a **Focus** in that discipline. For example, a student could select a Concentration in Evidence-based Clinical Effectiveness Research and a Focus in Nutrition or a Concentration in Clinical

Investigation and a Focus in Pharmacology. Approval of a Focus is made by the Program Director or the Associate Program Director.

For the Master of Science Degree, 19.5 credits are required which includes 17 credits in the core curriculum, 6 of which are from thesis work. In addition, 2.5 credits are earned from elective courses. A PhD student must complete at least 37.5 credits.

Most of the credits are from core courses: Biostatistics I and II, Study Design Seminar, Scientific Writing, Epidemiology, Ethics, and five courses within one of the six Concentrations, along with Mentored Evaluated Research/Thesis courses. A qualifying examination must be passed, normally at the start of year two, in order to become a PhD candidate. Additional courses may also be required as deemed necessary by the student and advisor for the dissertation. A minimum of three years is required for the PhD; the exact duration for an individual student will depend on the time required to complete an original and substantial dissertation of publishable quality.

Courses in the Clinical and Translational Science Graduate Program have proven to be of great interest to students outside of the Program and to students, postdoctoral fellows, and faculty throughout Tufts Medical Center and its affiliated hospitals, the Tufts University School of Medicine, Friedman School of Nutrition, the Sackler School of Graduate Biomedical Sciences, and other schools of Tufts University. Such individuals may enroll on a space-available basis; courses are also available to those not otherwise affiliated with Tufts, as space allows.

The Program faculty includes a broad range of experts in clinical investigation, clinical epidemiology, health services research, outcomes research, meta-analysis, biostatistics, and drug development, and many related fields drawn from the Tufts University and Tufts Medical Center community. This highly productive and committed faculty makes the Program an excellent environment for deep and broad training in clinical and translational research.

CURRICULUM OVERVIEW BY YEAR

Year One, Summer Semester, MS & PhD

CORE COURSES (credits earned):

CRES 525 Introduction to Clinical Care Research (2)
 CRES 540 Ethics of Clinical Investigation (.5)

<i>Year One, Fall Semester, MS & PhD</i>		<i>Year One, Spring Semester, MS & PhD</i>	
<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 515 Evaluated Research/Thesis (1) CRES 523 Introduction to Clinical Epidemiology (1) CRES 527 Biostatistics I (1) CRES 537 Scientific Manuscript Writing (.5) CRES 561 Introduction to Clinical Trials (.5)</p> <p style="text-align: center;">CRES Electives</p>	<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 515 Evaluated Research/Thesis (1) CRES 535 Biostatistics II (1) CRES 537 Scientific Manuscript Writing (.5) CRES 566 Introduction to Health Services Research (.5) CRES 581 Introduction to Meta-Analysis (.5)</p> <p>ELECTIVES:</p> <p style="text-align: center;">CRES Electives</p>		
<i>Year Two, Fall Semester, MS & PhD</i>		<i>Year Two, Spring Semester, MS & PhD</i>	
<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 516 Thesis Research (2) CRES 538 Scientific Grant Writing (.5)</p> <p>ELECTIVES:</p> <p style="text-align: center;">CRES Electives</p>	<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 516 Thesis Research (2) CRES 538 Scientific Grant Writing (.5)</p> <p>ELECTIVES:</p> <p style="text-align: center;">CRES Electives</p>		
PhD Students			
<i>Year Three, Fall Semester, PhD</i>		<i>Year Three, Spring Semester, PhD</i>	
<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 517 PhD Dissertation Research (4) CRES 539 Scientific Writing, Peer Review and Presentations (.5)</p> <p>ELECTIVES:</p> <p style="text-align: center;">CRES Electives</p>	<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 517 PhD Dissertation Research (4) CRES 539 Scientific Writing, Peer Review and Presentations (.5)</p> <p>ELECTIVES:</p> <p style="text-align: center;">CRES Electives</p>		
<i>Year Four, Fall Semester, PhD</i>		<i>Year Four, Spring Semester, PhD</i>	
<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 517 PhD Dissertation Research (4) CRES 539 Scientific Writing, Peer Review & Presentations (.5)</p>	<p>CORE COURSES (credits earned):</p> <p>CRES 500 Study Design Seminar (.5) CRES 517 PhD Dissertation Research (4) CRES 539 Scientific Writing, Peer Review & Presentations (.5)</p>		
<i>Year Five, Fall Semester, PhD</i>		<i>Year Five, Spring Semester, PhD</i>	
<p>Continued CORE COURSES (credits earned), if needed:</p> <p>CRES 500 Study Design Seminar (.5) CRES 517 PhD Dissertation Research (4) CRES 539 Scientific Writing, Peer Review & Presentations (.5)</p>	<p>Continued CORE COURSES (credits earned), if needed:</p> <p>CRES 500 Study Design Seminar (.5) CRES 517 PhD Dissertation Research (4) CRES 539 Scientific Writing, Peer Review & Presentations (.5)</p>		

*For the MS Degree, 19.5 credits are required which includes 12 core courses (17 credits in the core curriculum, 6 of which are from thesis work and 2.5 credits are earned from elective courses). A PhD student must complete at least 37.5 credits, 21 of which are from thesis work. Full-time matriculated students must be enrolled in courses for a total of 4 credits each semester.

REQUIRED CORE COURSES AND DESCRIPTIONS

CRES 500	Study Design Seminar (0.5)	CRES 537	Scientific Manuscript Writing (0.5)
CRES 515	Mentored Research/Thesis (1) (Year 1)	CRES 538	Scientific Grant Writing (0.5)
CRES 516	Thesis Research (2) (Year 2)	CRES 539	Scientific Writing, Peer Review & Presentations (0.5) (PhD)
CRES 517	PhD Dissertation Research (4) (PhD)	CRES 540	Ethics of Clinical Investigation (0.5)
CRES 523	Introduction to Clinical Epidemiology (1)	CRES 561	Introduction to Clinical Trials (0.5)
CRES 525	Introduction to Clinical Care Research (2)	CRES 566	Introduction to Health Services Research (0.5)
CRES 527	Biostatistics I (1)	CRES 581	Introduction to Meta-Analysis (0.5)
CRES 535	Biostatistics II (1)		

For the MS Degree, 19.5 credits are required which includes 12 core courses (17 credits in the core curriculum, 6 of which are from thesis work and 2.5 credits are earned from elective courses). A PhD student must complete at least 37.5 credits (21 of which are from thesis work). Full-time matriculated students must be enrolled in courses for a total of 4 credits each semester.

CRES 500 Study Design Seminar

(Kent, Pittas)

This year-long seminar, meeting weekly for one hour, uses proposed and ongoing research projects to explore issues in study design. The course format provides investigators and trainees the opportunity to present an ongoing research-related problem that they are encountering, and engages students in a discussion of the approach to the problem and construction of an appropriate plan of action. Over a year, wide ranges of research and study design problems are discussed, constituting a productive continuing educational experience for fellows and faculty alike. Participants learn to critique the varied works presented, and gain important insight into the research methodology of the hypothesis, study design, and analytical and statistical methods presented. Participants are evaluated based on their class participation.

CRES 515, 516, 517 Clinical Research Project/Thesis Research

(Appointed Faculty)

The fundamental precept of this graduate program is for the student to complete a comprehensive independent clinical research project, which includes framing a research question and specific project aims, identifying useful data sources, developing appropriate methods, identifying and defending against sources of bias, implementing/managing the project and writing the thesis in the form of a publishable article or monograph. The project's conduct must also be motivated and led by the student, so that the role of principal investigator is learned. Since we give the trainee more latitude and responsibility, progress will be carefully monitored to reduce the risk that a trainee may get bogged down or delayed from making timely progress. To practice reporting research activities and results, and good and frequent communication among colleagues, the monitoring process described below has ongoing reporting requirements that allow fellows to be monitored by mentors and the

Program Director. The purpose of these activities is to create a foundation for a long and productive career.

Therefore, unless otherwise agreed to by the student's Thesis Committee, Program/Career Mentor and Program Directors, the following activities will be required of each trainee:

1. Present a written draft of a project description to the Thesis Advisor, usually, but not always, the individual who is the Program/Career Mentor.
2. Select and secure written agreements from Project Mentor(s), the ones who will be on the Thesis Committee.
3. Present a written project proposal to the Thesis Committee and receive approval of project.
4. Provide regular (typically monthly) written updates of the thesis to the Thesis Advisor (chair of student's Thesis Committee) and written progress reports to student's entire Thesis Committee at least every six months and on the Committee's request.
5. Complete thesis research commensurate in originality and scale to the expected degree.
6. Write final report of completed thesis.
7. Present research project to Thesis Committee.
8. Write papers for publication.

Project Mentors are faculty members who have particular skills and resources that are important to a student's chosen project and who have agreed to work with the student on that project. Depending on the project and its needed resources, this mentoring typically will include several faculty members and additional individuals outside the Program, such as members of particular clinical areas, or special resources from the Tufts Medical Center or other Boston area academic, governmental, or health care communities, who are willing and able to facilitate a student's project. Although faculty have agreed to this role, it is part of the curriculum's philosophy of investigator-initiated collaboration that the student take significant responsibility for presenting an attractive proposal to Project Mentors that will motivate active, rather than merely passive, involvement in the student's project. The selection of a student's Project Mentors will be the joint responsibility of the student, his or her Program/Career Mentor, and the Program Director, in conjunction with the Project Mentor. (For detailed descriptions of mentors, see page 24 of this guide.)

A student's Thesis Committee consists of his or her Thesis Advisor and Committee members including appropriate experts agreed upon by the student, Program Director, and the proposed Committee member. This Committee will review the student's progress at the request of the student and will approve the required steps in completing the student's project as described above, including approval of the project, its protocol, and its progress, at intervals to be determined by the Committee. All such reviews will include both a meeting and a written review by the Committee. The chair of the student's Thesis Committee will be his or her Thesis Advisor.

CRES 523 Introduction to Clinical Epidemiology

(Paulus)

This course serves as an introduction to topics in epidemiologic study design and analysis. The major epidemiologic study designs will be examined, beginning with the randomized clinical trial as a paradigm. The course proceeds to examine observational designs, including ecologic, cross-sectional, cohort, and case-control studies. Sampling and analytical strategies, the appropriate measures of association and the biases specific to each study type will be covered. Principles and methods will be illustrated through in-class discussion of examples from the literature. Relevant statistical methods are introduced but not developed or implemented in detail.

CRES 525 Introduction to Clinical Care Research

(Kent)

This course, meeting three hours daily over a four-week summer session, teaches students how to formulate a clinical research hypothesis and to develop it into a clinical research project. Students acquire an understanding of basic and advanced principles of study design and issues in conducting biomedical research involving human subjects. The course includes introduction to fundamentals of clinical epidemiology and biostatistics, and also surveys topics in the other core Concentrations, including health services research, bench-to-bedside translational research, meta-analysis and decision analysis. A central theme of the course is how to develop a hypothesis into a feasible protocol. Students are required to develop a 3- to 5-page research proposal and to present this proposal to the class and faculty preceptors for scientific review. A summer lecture series on topics in clinical and health services research is also offered in conjunction with this course. Students are evaluated based on their participation, final project, and class exercises.

CRES 527 Biostatistics I

(Schmid)

This course introduces basic principles and applications of statistics to problems in clinical research. Topics covered include descriptive statistics, probability and random variation, sampling, hypothesis testing, proportions, measures of frequency, t-tests, chi-square tests, one-way analysis of variance, correlation, linear regression, and nonparametric statistics. Emphasis is on developing an understanding of the assumptions, limitations, and practical considerations in the use of statistical methods in research. Course time is split each week between classroom lectures and a computer lab to further explore issues. Students will acquire an understanding of the process of the statistical investigation of data used in the health professions. Participants will be able to apply the steps of statistical inference, select appropriate statistical tests, use computers to explore data and perform statistical tests, and to interpret the results and computer output for commonly used statistical procedures. Work will be judged from classroom participation, quizzes, examinations, and a written research project.

CRES 535 Biostatistics II

(Schmid)

This course surveys regression techniques for outcomes common in public health data, including continuous, binary, count, and survival data. Emphasis is on developing a conceptual understanding of the application of these techniques to solving problems and to cogently summarizing the results, rather than to numerical details. Topics covered include linear regression, multiple linear regression, logistic regression, poisson regression, negative binomial regression, longitudinal data and mixed models. Model building, model fitting, model checking, and inference are all stressed. Course time is split each week between classroom lectures and a computer laboratory in which students learn to apply their knowledge to productive data analysis. Students are evaluated by their classroom participation, a take-home midterm examination, an in-class final examination, and a 5- to 10-page original research project that includes data collection, proper statistical analysis and discussion of implications and limitations of the study.

CRES 537 Scientific Manuscript Writing

(Goldberg)

This course focuses on principles of scientific manuscript writing. The student will learn how to develop a manuscript by reviewing the specific issues of style, authorship, and volume of information that should be incorporated into a research paper. Other topics covered in depth include the impact on/of existing literature, the investigator's role in the scientific community, and the promotion process of writing articles on the "minimum publishable unit" versus more comprehensive works.

CRES 538 Scientific Grant Writing

(Goldberg)

The purpose of this course is to teach the principles of clinical research grant writing. Participants will learn the importance of, and how to select, investigators, and co-investigators as well as the identification of potential funding sources along with other important aspects of grant writing.

CRES 539 Scientific Writing, Peer Review & Presentations

(Appointed Faculty)

Students will focus on principles of scientific review and grant peer review. This will involve critiquing manuscripts and reviewing research grants for mock study section meetings. Students will also be encouraged and given an opportunity to present their scientific writings and oral presentations for critique on an ongoing basis.

CRES 540 Ethics of Clinical Investigation

(Parsons)

This course's goal is to increase awareness of research ethics and their practical applications by medical practitioners and researchers, specifically with regard to clinical investigations. The curriculum will address the interrelationships between ethics, law, and professional practice standards and will explore the role and workings of Institutional Review Boards (IRBs). Basic

ethics principles will be introduced and their connections with various research regulations and practices (such as informed consent) will be reviewed. The course materials are designed to help students recognize potential conflicts of interest that may arise in clinical research and to understand the requirements and ethical underpinnings for the responsible conduct of research. To help in applying research and professional ethics in practice, the course provides a framework for thinking about ethical dilemmas and responding to them. This is a seminar course and evaluations are based on class participation and written assignments.

CRES 561 Introduction to Clinical Trials

(Snydman)

This course considers the various problems and options available in the design and conduct of clinical trials, including classical efficacy trials and "effectiveness trials." Issues to be covered include ethics, experimental design, coordination and operations, database development, interim analysis and safety monitoring and analysis and reporting. Examples will be based on ongoing trials being run by the faculty. Students will develop a design for a trial and its analysis, which will be a major component of their evaluation.

CRES 566 Introduction to Health Services Research

(Lerner)

This course will introduce students to the concepts and methods that distinguish health services and health policy research from other fields. Faculty will cover major topics in health services/health policy research including outcomes research design and methods, health economics, pharmacoconomics, access and payment for health services, and healthcare quality and quality improvement. Students will be graded principally on participation in classroom discussions, periodic assignments in which students are asked to provide a critical analysis of a study discussed in class, and a final examination in which students design a health services/health policy research project that builds upon one or more of the themes addressed during the course.

CRES 581 Introduction to Meta-Analysis

(Balk, Terrin, Uhlrig)

This course covers the principles of systematic review processes, evaluation of studies and bodies of evidence as used in the conduct of systematic reviews, meta-analyses, and the development of evidence based clinical practice guidelines. The course will focus on studies of treatment efficacy. The course introduces the basic conceptual framework of analysis, provides examples, and discusses different approaches and work in the field. Topics covered include developing a research protocol, searching the literature, extraction of data, methods for pooling and statistical analysis, grading study quality, clinical and statistical heterogeneity, publication bias, meta-regression, and appraisal of bodies of evidence. Homework includes data analyses, weekly reading assignments, preparation of presentations on systematic reviews in the literature, and the drafting of a project proposal for a systematic review. Students are evaluated based on participation in class and successful completion of the homework.

PHD QUALIFYING EXAM

If a student is interested in pursuing the PhD in Clinical Research, he or she will need to successfully pass the Qualifying Exam, which is generally administered the summer after the student's first year of study in the Program. The Qualifying Exam consists of two parts, a general competency exam and a written study protocol with an oral presentation. The overall objective of the exam is to evaluate a candidate's competency in basic skills and knowledge to conduct clinical research as well as ability to develop and formulate a research project. Within three months after successfully passing the qualifying exam, he or she must present a dissertation proposal in the format of a research grant to the Program's Advisory Committee.

CONCENTRATIONS

Students are required to take core courses essential to developing the necessary competencies to become independent researchers. This includes mastery of principles and methods of epidemiology and biostatistics, to allow students to be able to critically evaluate and analyze data, and to design rigorous studies and develop new methods, as well as to master specific methods and approaches that are central to their Concentration. Students elect a concentration (described below) to develop a greater depth of knowledge and skills in a selected area. In addition to selecting a thesis relevant to that Concentration, students work with the Concentration Leader to identify electives and/or projects to develop the competencies for that area.

Students in the Clinical and Translational Science Graduate Program may elect one of three **Concentrations:**

Evidence-based Clinical Effectiveness Research

This Concentration includes the areas known as CER, EBM, and related areas that advance the translation of information about the effectiveness of treatments and healthcare strategies into practice. Consistent with the definition from the Institute of Medicine Report on Priorities for CER (2009), they focus on “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policymakers to make informed decisions that will improve health care at both the individual and population levels.” Besides covering a broad span of work that could meet that definition, this Concentration focuses on learning about the methodologies and applications of systematic review and meta-analysis, and on the development of clinical practice guidelines as the tools to practice evidence-based healthcare.

Clinical Investigation

This Concentration is intended for clinician-investigators desiring methodologic grounding for the full range of patient-oriented clinical research including randomized controlled trials, and Phase I, II, and III trials. The concentration includes exposure to many of the tenets of evidence-based medicine and epidemiology as well as drug development and study design. The Concentration spans from bench-to-bedside translational research and first-in-humans clinical trials to later phase clinical efficacy and effectiveness trials, including all types of therapeutic and diagnostic approaches. Thus this Concentration provides collaborative interdisciplinary training in basic biomedical and clinical research methodologies for the translation of the basic molecular pathophysiology of diseases to clinically meaningful applications, opportunities to do early-phase clinical studies in the Tufts CTSI Clinical and Translational Research Center (CTRC), and broad and rigorous training in clinical trial design and conduct to address a wide range of clinical questions.

Health Services and Outcomes Research

This Concentration emphasizes application of a variety of methods to the investigation of population health improvement and the organization, delivery, financing, and outcomes of health care services. This work can include a variety of interventions in healthcare delivery and health promotion, organizational work, and policy and economic analyses and interventions. It also can include the application of informatics to healthcare. Thus this Concentration can include focuses on the intersection between computer science and medicine, in particular information management and technologies for clinical research to improve health outcomes through the use of patient-centered, evidence-based, clinical decision-making strategies.

ELECTIVE COURSES WITH CONCENTRATIONS

ELECTIVE COURSES	Concentrations		
	Clinical Investigation	Evidence- Based Clinical Effectiveness Research	Health Services & Outcomes Research
CRES 501 Translational & Molecular Epidemiology (0.5)	X	X	
CRES 502 Bridging the Bench to Bedside Gap (.5)	X		
CRES 504 Basic Biostatistics / Quantitative Reason (1)	X	X	X
CRES 510 Predictive Models for Health Outcomes (1)	X	X	X
CRES 519 Concentration Practicum (variable)	X	X	X
CRES 530 Advanced Topics in Biostatistics (1)	X	X	X
CRES 545 Psychometrics & Outcomes Measurement (1)	X	X	X
CRES 555 Principles of Drug Development (1)	X	X	X
CRES 556 Principles of Pharmacoeconomics (0.5)	X	X	X
CRES 562 Special Topics in Clinical Trials (0.5)	X	X	X
CRES 567 Health Policy (0.5)		X	X
CRES 571 Advanced Epidemiology (1)	X	X	X
CRES 582 Genetic Epidemiology (1)	X	X	
CRES 584 Introduction to Decision Analysis (0.5)		X	X
<p>CRES Electives are not offered on annual basis. An interest survey of incoming second year students determines CRES Elective course offerings. In addition to CRES Electives, students may, with the permission of their Program Mentor, enroll in electives offered by other Tufts University graduate programs.</p>			

Each course description includes a designation (noted below) that it is an Elective course representing the Concentration(s) to which it applies. Other electives may be offered upon demand.

ELECTIVE COURSES

CRES 501 Translational and Molecular Epidemiology

(Ioannidis) [CI, EBCER]*

This course will aim to address some of the main challenges of current translational research in the interface of epidemiology and molecular medicine. We will discuss issues of efficiency of translational research, characteristic milestones in the translational pipeline, credibility of research findings, causal pathways, intermediate and surrogate markers, replication and validation, sources of bias in molecular research and diagnostics for bias, Mendelian randomization and structural modeling, large-scale molecular evidence, meta-analysis in molecular epidemiology, grading of evidence in translational research, and issues of large-scale multi-center studies and international collaborative efforts in this broad domain. We will draw examples from molecular genetics of gene-disease association studies, including whole genome association analyses, microarrays, proteomics, and other molecular markers. Examples of applications in diagnosis, prognosis/prediction, and preventive/therapeutic intervention will be discussed. The course assumes knowledge of basic concepts of clinical epidemiology and basic concepts of medical statistics, but no advanced mathematics are required.

CRES 502 Bridging the Bench to Bedside Gap

(Huggins) [CI]

This course seeks to diminish the "bench- to-bedside" gap by bringing clinical graduate students into the world of basic science research. Students focus on the major questions that are ripe for future scientific investigation; how scientific discoveries have influenced clinical practice; and how clinical practice has affected basic research. Examination of active projects at Tufts Medical Center will introduce students to translational science in action.

CRES 504 Basic Biostatistics / Quantitative Reasoning

(Griffith) [This course is a Certificate Program requirement and an elective for MS/PhD program students.]

This course presents the practical application of biostatistical methods for exploring and analyzing health data. Methods for working with data and exploring basic associations are presented through case examples and clinical research projects.

CRES 510 Predictive Models for Health Outcomes

(Griffith, Kent) [CI, EBCER, HSR]

This course explores the use of statistical models to predict clinical outcomes for retrospective review and as prospective decision aids. Emphasis is placed on integrating statistical and clinical thinking to construct models that are both statistically and clinically sound and that give accurate predictions when generalized to other populations. Methods for model construction and modeling issues (e.g., missing data, performance evaluation) are explored. The course follows a workshop format, with students presenting work in progress, allowing them to

* Initials in brackets indicate for which Concentrations the elective typically applies. CI = Clinical Investigation, EBCER = Evidence-Based Clinical Effectiveness Research, and HSR = Health Services and Outcomes Research.

develop oral and written presentation skills, to learn how to critique their own and each others' work, and to interact with faculty. Students will be evaluated on their participation and on a course project.

CRES 519 Concentration Practicum

(Faculty) [CI, EBCER, HSR]

Students are required to take core courses essential to developing the necessary competencies to become independent clinical researchers. In addition, students may elect a Concentration (Bench-to-Bedside Translational Research, Clinical Investigation, Epidemiology and Biostatistics, Evidence-based Medicine, Health Services and Outcomes Research, and Medical Informatics) to develop a greater depth of knowledge and skills in a selected area. In addition to selecting a thesis topic relevant to that Concentration, the student works with the Concentration Leader to identify electives and/or projects to develop competencies in that area. Therefore, this is an elective to develop greater knowledge and skills regarding the selected Concentration.

CRES 530 Advanced Topics in Biostatistics

(Schmid) [CI, EBCER, HSR]

This seminar covers topics selected by the instructor based on the statistical research needs of students. Possible choices include factor and principal components analysis, longitudinal data models, neural networks, time-series analysis, and advanced survival analytic methods. The structure of the seminar is flexible to allow participants the opportunities to explore in depth advanced statistical topics and to provide specific analytic skills of use to participants in their own research. A final project analyzing data with one of the covered techniques is required.

CRES 545 Psychometrics and Outcomes Measurement

(Lerner) [CI, EBCER, HSR]

This course will review health assessment tools and other patient-reported outcome measures that are used to ascertain functional health, well-being and health-related quality of life. Students will become familiar with the role of self-report measurement in clinical research and specific measurement tools. Students will learn psychometric methods for developing a reliable, valid, practical and meaningful measurement tool, including quantitative and qualitative techniques.

CRES 555 Principles of Drug Development

(Kaitin) [CI, EBCER, HSR]

This course will examine the important economic, political, legal, and scientific issues that face academic clinical investigators who work in partnership with industry sponsors and government regulators to design and conduct clinical studies. Lectures by academic and industry experts will cover a broad range of topics, including FDA history and the regulation of drug development, regulatory and legislative initiatives to foster innovation for breakthrough medicines, persistence and compliance in clinical study design, information technology in clinical trials, the investigative site landscape, reimbursement and drug access, Good Clinical Practice guidelines, and the role of specialty pharmaceuticals. There will also be a lecture on making the transition from a career in academics to one in industry. The course will be taught

in seminar format. Students will be expected to participate in all seminar discussions and make a presentation to the class on a pertinent topic; the topic will be chosen in consultation with the course director.

CRES 556 Principles of Pharmacoeconomics

(Neumann) [CI, EBCER, HSR]

This course focuses on methods and uses of pharmacoeconomic analyses (and other economic evaluations of medical technologies) in health care. Pharmacoeconomics is the application of economic evaluation (i.e., cost analysis, cost-effectiveness, cost-benefit analysis, etc.) to pharmaceutical therapies. The course includes case studies in different disease areas which serve to highlight key methodological and strategic issues in the field. The course also includes lectures on the pharmaceutical industry, FDA approval and the regulatory process, and coverage, reimbursement, and pricing issues in the United States and abroad.

CRES 562 Special Topics in Clinical Trials

(Snydman) [CI, EBCER]

This is a seminar course that will explore special topics in clinical trials. Topics include Internet based clinical trials, N-of-1 trials, trials in special populations and overseas, industry sponsored trials, and multicenter trials

CRES 567 Health Policy

(Lerner) [EBCER, HSR]

This course examines the forces that influence the health policy process in terms of policy formulation, implementation and outcomes. Consideration is given to the roles of various stakeholders: healthcare professionals, consumers, and public and private payors.

CRES 571 Advanced Epidemiology

(Paulus) [CI, HSR]

This course serves as an introduction to more advanced topics in epidemiologic study design and analysis. This course starts with a module on study design, beginning with the randomized clinical trial as a paradigm, and proceeding to examine observational designs in depth, including prospective and retrospective cohorts, and those sampling from an underlying cohort (case-control, case-crossover and case-cohort studies). Design, sampling and analysis strategies and the biases that are specific to each study type will be discussed. The second course module examines topics in study analysis, interpretation and bias, including confounding, matching, propensity scores, instrumental variables, effect modification, misclassification, and directed acyclic graphs for causal inference. Principles and methods will be illustrated through in-class discussion of examples from the literature. Relevant statistical methods are introduced but not developed or implemented in detail. A prior introductory course in epidemiology is required for enrollment.

CRES 582 Genetic Epidemiology

(Paulus) [CI]

This course serves as an introduction to the field of genetic and molecular epidemiology. Concepts key to genetic association studies will be presented, including basic molecular and population genetics, single marker selection, linkage disequilibrium, haplotype analysis, gene-gene and gene-environment interaction, genome-wide association studies, and multiple comparisons issues. Family-based linkage studies will also be introduced. The course will conclude with consideration of implications for clinical practice and the emerging field of personalized medicine. Real-world illuminating examples of these research approaches will be presented alongside review of concepts on design and analysis. Some of the practical tools necessary for these studies will also be introduced in classroom and computer lab sessions, including marker selection algorithms, genome browsers, and software packages to explore population stratification and power calculations. A prior introductory course in epidemiology is recommended but not required for enrollment.

CRES 584 Introduction to Decision Analysis

(Pauker, Wong) [CI, HSR, EBCER]

This course is a working overview of the principles of decision analysis as applied to medicine, making optimal choices in the face of uncertainty. Formal decision analysis has become a well-recognized and accepted research discipline for examining clinical options facing patients, physicians, and policymakers. Course content includes the interpretation of clinical data and test results, the analysis of the risks and benefits of testing and treatment, estimating prognosis, and determining preferences for outcomes. Topics include the basic conceptual framework of decision analysis, diagnostic test interpretation, decision tree construction and evaluation including Markov models and Monte Carlo simulations, life expectancy estimation, quality of life assessment, and cost-effectiveness analysis. The goal of the course is to introduce students to the methodological components of decision and cost-effectiveness analyses.

CERTIFICATE PROGRAM IN CLINICAL AND TRANSLATIONAL SCIENCE

In 2009, Tufts University Sackler School of Graduate Biomedical Sciences introduced the Tufts Certificate Program in Clinical and Translational Science (CTS). This program is designed to provide a basic foundation in clinical research for physicians and other doctorally-trained clinicians who are unable to devote two or more years of full-time study to obtain an MS or PhD degree. The Program is designed to be compatible with a part-time commitment for one academic year.

Eligibility

The Tufts Certificate Program in CTS is intended for individuals already trained in the medical sciences, primarily fully-trained physicians, but also others with analogous backgrounds (e.g., DDS, DVM) who want further training for research careers. The Program specifically targets junior faculty of Tufts-affiliated hospitals, as well as fellows in training, or mid-career clinicians who are considering a career change and want to strengthen their clinical research skills.

Curriculum

The Certificate Program in CTS builds on the infrastructure and courses of the existing Sackler MS/PhD in Clinical and Translational Science Graduate Program and the topics covered are those believed to be essential for any researcher. The Certificate Program, which has much of the same course work, is compatible with a part-time commitment of one academic year.

There are no elective courses in the Certificate Program, although the tailored mentored research project is intended to provide some flexibility for the student to individualize the educational experience. Plus, many courses leverage the students' individual research interests and projects.

The Certificate Program begins with a summer program that combines the Introduction to Clinical Care Research with a newly designed course specific to the Certificate Program: Understanding Biostatistical Methods. This course in quantitative reasoning is tailored to clinicians and is unique on the Tufts campus. It includes both basic statistical concepts and principles, and an introduction to the interpretation of data from clinical studies, with special attention to issues of bias and confounding in the medical literature. In addition to these courses, the students also complete Ethics of Clinical Investigation and a mock IRB and Scientific Review. All students are responsible for developing a brief research protocol during the summer semester which frequently forms the basis for the student's mentored research throughout the year. The remainder of the curriculum is outlined in the Table below.

**CERTIFICATE PROGRAM CURRICULUM
OVERVIEW BY SEMESTER**

Summer Semester

CORE COURSES (credits earned):

CRES 525 Introduction to Clinical Care Research (2)
 CRES 540 Ethics of Clinical Investigation (.5)
 CRES 504 Understanding Biostatistical Methods (1)

Fall Semester

CORE COURSES (credits earned):

CRES 523 Introduction to Clinical Epidemiology (1)
 CRES 500 Study Design Seminar (.5)
 CRES 561 Introduction to Clinical Trials (.5)

OTHER:

Biostatistics online refresher module (0)

Spring Semester

CORE COURSES (credits earned):

CRES 500 Study Design Seminar (.5)
 CRES 566 Introduction to Health Services Research (.5)
 CRES 581 Introduction to Systematic Review and Meta-analysis (.5)
 CRES 515 Mentored Research (1)

Additional Requirements

- Participation in spring Clinical and Translational Science Graduate Program Symposium: Poster Presentation
- Customized final project agreed upon at the beginning of spring semester (examples include: publishable manuscript/brief report, proposal for pilot project, etc.)
- Mentoring: Potential mentors will be identified during the recruitment and admission process in the spring prior to enrollment
- Statistical software: SPSS
- Total Credits: 8 credits (all credits may be applied toward the 19.5 credits required for Master of Science Degree, for those electing to matriculate)

ADMISSIONS

The Clinical and Translational Science Graduate Program is intended for physicians or other doctorally prepared clinicians (e.g., DDS, PharmD) who have completed clinical training and want further training for a research career to become independent investigators and leaders in their fields of research. A limited number of fellowships are available that provide a stipend and tuition.

There is a yearly application period during which time applications must be made online. Acceptance decisions are made each spring. The Program begins in July of each year.

For Application and Instructions:

<http://www.tufts.edu/sackler/programIntros/clinical.html>

For Additional Program Information:

<http://www.tuftsctsi.org/Education-and-Career-Development/Clinical-and-Translational-Science-Graduate-Program.aspx>

Contact Information:

Nina Bonnoyer
Education Coordinator
Clinical and Translational Science Graduate Program
Tufts Medical Center
800 Washington Street Box #63
Boston, MA 02111, United States
Phone: 617-636-4999
Fax: 617-636-0525
nbonnoyer@tuftsmedicalcenter.org

CROSS REGISTRATION

Electives are offered each term within the Program and should be given first consideration. However, if an elective is not being offered at the Clinical and Translational Science Program, matriculated students may take one course per semester for both a grade and credit through cross-registration with the Universities listed below. This is subject to the consent of the course instructor, the student's program mentor, and registrars from each program.

Cross Registration Universities

Full-time matriculated students in the institutions below may cross-register for one course per semester for the fall and spring semesters only. This is subject to the consent of the course instructor, both registrars, and for Sackler students, their faculty advisors. Approved forms will be accepted according to the schedule of the host institution. Enrollment in any course is subject to prerequisites, attendance policies, and the academic calendar of the host institution.

Tufts University

- The Cummings School of Veterinary Medicine
- Fletcher School of Law and Diplomacy
- The Friedman School of Nutrition Science and Policy
- The Graduate School of Art, Sciences & Engineering
- School of Medicine

Boston College

Boston University

Brandeis University

Tufts University

When cross registering at Tufts University, please email the faculty member teaching the course for approval before the course starts. Go to the Sackler School website for complete guidelines and forms at <http://www.tufts.edu/sackler/currentStudents/forms.html>. An add/drop form is required if you wish to take another Biomedical Sciences course that is not in your program. Go to the Sackler School website for complete guidelines and forms (as above).

Cross-listed Courses within Tufts

Matriculated Sackler students who wish to take courses that are cross-listed with the Tufts University School of Medicine should register through the Sackler School using the Sackler course designator and number. The Sackler School will provide Tufts University School of Medicine Office of Educational Affairs with a list of students enrolling in cross-listed courses each term to insure that A-F grades are assigned to the Sackler students. The Cross-Registration Request form is not required for cross-listed courses.

Other Universities

If you are cross registering outside of Tufts University, please use the following instructions:

- Please email instructor of the course to receive approval.
- Registrars at both universities should be contacted for specific instructions. If possible, use the Tufts University cross-registration form. Copies of the completed form should be sent to each registrar and the education coordinator of the Tufts Clinical and Translational Science Graduate Program. Plus, follow-up with each registrar's office to confirm registration is strongly recommended.
- When the course is completed and a grade assigned, the student should obtain a copy of the transcript for the Tufts Registrar for the grade to be applied to the student's Tufts University transcript.

Cross-Registration Universities Contact Information:

Boston College

Office of Student Services: <http://www.bc.edu/offices/stserv/>

To find courses: <http://www.bc.edu/offices/stserv/academic/univcat/>

Location:

Office of Student Services

Lyons Hall

140 Commonwealth Avenue

Chestnut Hill, MA 02467

Phone: 617-552-3300 or 800-294-0294

Fax: 617-552-4889

Email: studentservices@bc.edu

URL: <http://www.bc.edu/offices/stserv/>

Boston University

BU Instructions: <http://www.bu.edu/reg/graphics/xrgdocsprg-nonbu.pdf>

To find courses: <http://www.bu.edu/reg/>

Office of the University Registrar

881 Commonwealth Avenue

Boston, MA 02215

Phone: 617-353-3612

Fax: 617-358-1689

Email: registrar@bu.edu

URL: www.bu.edu/reg

Brandeis University

To find courses: <http://www.brandeis.edu/registrar/>

Office Location:

124 Kutz Hall

Waltham, MA 02453

Phone: 781-736-2010

Fax: 781-736-3485

Email: registrar@brandeis.edu

Office Hours:

9:00 a.m. - 5:00 p.m., Monday to Friday

PROGRAM MENTORS

Mentors

The Graduate Program incorporates faculty mentoring for both career development (Program Mentor) as well as for specific research projects (Project Mentor).

Program Mentors

Each fellow will have a designated Program/Career Mentor who will serve to ensure that the fellow's experience in the Program is optimal. This faculty member will take primary responsibility for mentoring the fellow in his/her career plans and development. (In many cases, the Program Mentor is assigned by a student's individual training program.) The primary responsibility of the Program/Career Mentor is to ensure that the fellow receives the necessary support for his/her development and matures professionally. Although primarily a training program role, it is anticipated that these faculty members will also act as general role models for fellows, demonstrating by their approach to research the work styles and commitment to ethical conduct that will serve their professional and personal lives well in the decades following graduation.

Program Mentors should be identified early in the first semester of the first year of study.

Project Mentors

Project Mentors are faculty who have particular skills and resources that are important to a student's chosen project and who have agreed to work with the student on that project. Depending on the project and its needed resources, this mentoring may include several faculty members and individuals outside the Program, such as members of particular clinical areas, or special resources from the Tufts Medical Center or other Boston area academic, governmental, or health care communities, who are willing and able to facilitate a student's project. The Program—in keeping with its commitment to developing independent investigators—expects that a student take significant responsibility for presenting proposals to prospective Project Mentors that will motivate their active, rather than passive, involvement in student's projects. Selection of a student's Project Mentors will be the joint responsibility of the student, his or her Program/Career Mentor, and the Program Director, in conjunction with the Project Mentors. Project Mentors constitute the faculty for the course in Mentored Research (CRES 515) taken in the fall and spring semesters of the first year.

Statistical Mentors

Each student is assigned a Statistical Mentor upon entry into the Program. As his/her research agenda and interests develop through the course of study, change in Statistical Mentors may be appropriate, and frequently occurs. However, before initiating any changes, the student must talk with the Associate Program Director.

Thesis Chair

As the student progresses in the MS or PhD programs, he/she will select a Chair for his/her thesis or committee. Often, a Project Mentor with whom the student worked in the first year

will agree to chair a thesis committee. The Thesis Committee Chair should be a member of the Sackler Faculty.

The major responsibilities of the Thesis Chair are to provide timely advice and critical feedback regarding design and execution of the research, and to advocate for the thesis and the student in meetings of the Advisory Committee and the Sackler Faculty.

The Thesis Chair should be identified by the end of the first semester of study.

POLICY ON THESIS/DISSERTATION FORMAT FOR CLINICAL AND TRANSLATIONAL RESEARCH

The purpose of the thesis or dissertation is to demonstrate research competence as a culminating project of the Clinical and Translational Science Graduate Program. Working under the supervision of the Thesis Committee, the student's work must be original and rigorous and approved by the student's Thesis Committee and the Clinical and Translational Science Graduate Program Advisory Committee in order to graduate.

Publishing research is an important element of the scientific research process. In order to encourage publication of the thesis or dissertation research findings, the Clinical and Translational Science Graduate Program will now accept either a publishable/published manuscript format or a traditional monograph format. While the work of the thesis or dissertation is the same for either option, students are encouraged to use the publishable format as a way to enhance their scholarship record regarding clinical research, translational research or health policy research. Using that option, one article is required for the master's thesis (original research findings) and a minimum of three articles are required for the dissertation (at least one of which must present original research findings).

For journal publication, two to three high-quality peer review journals must be identified for each planned manuscript in the initial proposal and approved by the Thesis Committee. On occasion, a paper may have been published prior to submission of the dissertation, in which case the published version may be included in lieu of a typescript. However, papers submitted as part of a thesis or dissertation may not have been published prior to the student's matriculation into the Program, and the majority of the work must be completed after matriculation under the supervision of a faculty member.

For PhD dissertations submitted in the form of publishable papers, the three publishable/published papers should be related, either by their substantive content or methodology, and constitute a cohesive whole. Each manuscript should be accompanied by its own appendices. In addition, dissertations must include an introductory chapter outlining the problem and establishing the purpose and objectives of the work as a whole and for each of the manuscripts and a final chapter providing an overview summarizing and synthesizing the manuscripts.

FACULTY

David A. Adler, MD

Dr. Adler, Professor of Psychiatry and Medicine, leads a mental health services outcomes group that has been involved in a broad array of mental health outcomes assessments. He has been both a Principal Investigator and Co-PI on a number of federally funded studies of the detection and treatment of depression in both primary care and the work place as well as a technical expert for our AHRQ Evidence-based Practice Center. Dr. Adler has 30 years of experience as a master clinician, teacher, supervisor, and consultant at numerous institutions including Tufts Medical Center, Tufts University School of Medicine, Simmons School of Social Work, Bay Cove Human Services, Bay Cove Mental Health Center, The Levinson Institute, and many community health agencies. His extensive writings and numerous lectures have spanned the areas of psychopathology (particularly schizophrenia and personality disorders), health policy, psychotherapy, mental health services, and outcomes assessment.

Alawi Alsheikh-Ali, MD, MS

Dr. Alsheikh-Ali holds a joint faculty appointment at the Institute for Clinical Research and Health Policy Studies and the Division of Cardiology at Tufts Medical Center. He is Assistant Professor of Medicine at Tufts University School of Medicine, and an attending cardiac electrophysiologist at the New England Cardiac Arrhythmia Center at Tufts Medical Center. He is the recipient of a faculty development award from Tufts Medical Center/Pfizer. His research interests have included work on the tolerability of lipid altering drugs in the general population based on the US FDA adverse event reporting system, and on the determinants of benefit and drug toxicity in lipid intervention trials. Currently, his primary research interest is in the effect of competing causes of mortality on the efficacy of the implantable defibrillator in patients with heart failure, and in risk stratification and long-term outcomes of patients with implantable defibrillators in common clinical practice.

Ethan M. Balk, MD, MPH

Dr. Balk, Assistant Professor of Medicine, is a Clinical Investigator in the Institute for Clinical Research and Health Policy Studies. His current research is systematic review, meta-analysis, quality assessment, and clinical guideline development. He is the Associate Director of the Center for Clinical Evidence Synthesis and the Tufts Medical Center Evidence-based Practice Center, and the Director of the Evidence-based Medicine of the Tufts Center for Kidney Disease Guideline Development and Implementation. He is a graduate of the Division of Clinical Care Research Health Services Research Postdoctoral Fellowship Program and, prior to joining Tufts Medical Center, was an internist at a multispecialist clinic in suburban Boston.

Jennifer Bassett Midle, MPH

Ms. Bassett Midle, member of the BRC since 2005, is a research statistician at Tufts-NEMC. She provides data management and statistical analysis for a large community-based study investigating the relationship between bone density, stress, and nutrition and also collaborates with clinical researchers throughout the Tufts-NEMC community and affiliated institutions. In addition, Ms. Bassett Midle teaches the SAS computer sessions in the biostatistics sequence of

the Sackler Clinical Research program. She has a Master's in Public Health from Columbia University, Mailman School of Public Health.

Evan M. Benjamin, MD

Dr. Benjamin is Associate Professor of Medicine at Tufts University School of Medicine and Vice President for Healthcare Quality for Baystate Health System in Springfield, Massachusetts. Dr. Benjamin attended Case Western Reserve University School of Medicine in Cleveland, OH, and completed the Internal Medicine Residency Program at Yale-New Haven Hospital, Yale University School of Medicine. Dr. Benjamin directs the Division of Healthcare Quality at Baystate Medical Center where he oversees the operations and research goals of the division. His research interests are in patient safety and quality improvement with a particular interest in diabetes care. He has been an innovator for using clinical practice guidelines to improve the translation of research into practice in a number of settings. His work using large databases to identify Quality of Care issues has been published in respected peer reviewed journals. His division has won a number of national awards for advancing the patient safety movement. Dr. Benjamin speaks nationally regarding the impact of our healthcare delivery system on the quality of healthcare. He serves on a number of advisory panels, editorial boards, and national committees.

Joni R. Beshansky, RN, MPH

Ms. Beshansky, Assistant Professor of Medicine and Assistant Professor of Family Medicine and Community Health, is a Research Scientist with extensive experience in the conduct of clinical effectiveness trials. As the Project Director for these large trials (28-hospital 3,500-subject Thrombolytic Predictive Instrument Clinical Trial; 7-hospital 2,500-subject ED Sestamibi Clinical Trial and the 10-hospital 10,700-subject ACI-TIPI Clinical Trial), she is closely involved in trial design, development of data collection forms, study protocols and procedures, and implementation of multisite clinical trials.

Kathleen M. Bungay, RPh, PharmD, MS, FCCP

Dr. Bungay is an Assistant Professor of Psychiatry and Medicine, member of The Health Institute, and Clinical Pharmacist at Tufts Medical Center. She has been affiliated with research involving pharmaceutical products, clinical pharmacy services and mental health services research for the past 20 years. Her areas of professional interest are in improving care for people with mental illness, medication adherence, and pharmacy practice. She was awarded a K 23 award from the NIMH (MH-068634) to study antidepressant use in elderly patients using both quantitative and qualitative research techniques. Prior to that, she was Senior Project Director for an NIMH study on Improving Depression Treatment/Outcomes in Primary Care; this RCT tested the impact of a pharmacist intervention on the depression outcomes in patients in primary care.

Peter Castaldi, MD, MS

Dr. Castaldi graduated with a BA from Princeton University and an MD from the University of Massachusetts Medical School. He completed a residency in internal medicine and served as chief resident at Tufts Medical Center. Dr. Castaldi graduated from the Tufts University Sackler

School of Graduate Biomedical Sciences Clinical Research Program in 2008. His research focuses on two areas related to COPD: COPD genomics and COPD inhaler adherence.

Hong Chang, PhD

Dr. Chang, a member of the Biostatistics Research Center since 2001, is Assistant Professor of Medicine at Tufts University and member of the Special and Scientific Staff at Tufts Medical Center. He serves as a Statistician at The Health Institute in Institute for Clinical Research and Health Policy Studies, and processes primary care assessment surveys. Prior to this, Dr. Chang was a consultant at the Health Care Consumer Survey unit of Coopers & Lybrand LLP, where his primary duties were conducting statistical analysis, assisting in the design of survey instruments, implementing the sampling strategies, as well as maintaining a rich database built upon previous surveys. Dr. Chang earned his PhD in statistics from the University of Connecticut.

Joshua T. Cohen, PhD

Dr. Cohen is a Research Associate Professor of Medicine at the Tufts Medical Center Institute for Clinical Research and Health Policy Studies, and Deputy Director of the Center for the Evaluation of Value and Risk in Health. His research focuses on the application of decision analytic techniques to public health risk management problems with an emphasis on quantifying the risks, benefits, and costs of public health interventions. This work has included an analysis of the health benefits and net costs of screening programs to identify Alzheimer's disease patients, an evaluation of the return on investments in preventive care interventions, and a comparison of the risks and benefits associated with shifts in population fish consumption patterns. Dr. Cohen recently served on a National Academy of Sciences committee charged with evaluating US EPA's methodology for estimating environmental health risks. He currently serves on the Massachusetts Department of Elementary and Secondary Education panel that is rewriting the Commonwealth's K-12 mathematics curriculum framework. Dr. Cohen received both his PhD in Decision Sciences and his BA in Applied Mathematics from Harvard University.

Thomas W. Concannon, PhD, MA

Dr. Concannon studies the organization of healthcare services for high-cost and high-intensity patients. His recent research has focused on strategies to regionalize pre-hospital emergency care for patients with heart disease. He has expertise in geographic information systems (GIS), comparative effectiveness, and cost effectiveness research. Dr. Concannon is also interested in research aimed at translation of known clinical interventions into effective health services strategies. Dr. Concannon received his PhD in Health Policy from Harvard University and MA in Political Science from McGill University. He is a recipient of the National Research Service Award and the Sidney R. Knafel Dissertation Completion Fellowship. Prior to pursuing his PhD, Dr. Concannon was a staff consultant at John Snow, Inc., where he worked with Ryan White CARE Act-funded health departments, hospitals and clinics to improve federally-funded care for people living with HIV and AIDS.

Jan L. Cook, MD, MPH

Dr. Cook, Adjunct Assistant Professor of Medicine, is the Medical Director of Quality and Health Improvement Programs at Blue Cross and Blue Shield of Massachusetts (BCBSMA). She oversees the production of BCBSMA population analyses, the development and evaluation of network clinical improvement projects, and oversees the NCQA and HCFA quality accreditation projects and clinical guidelines development.

Ralph B. D'Agostino, PhD

Dr. D'Agostino, Professor of Mathematics and Statistics at Boston University, is the Director of Statistics for the Framingham Heart Study, has completed his role as Chairman of the Nonprescription Drug Advisory Committee at the Food and Drug Administration and is involved in a wide array of clinical health services research studies. Besides his interests in mathematical modeling and cardiovascular disease, he has made fundamental contributions to biostatistical methods.

Olaf Dammann, MD

Dr. Dammann is a pediatrician and epidemiologist with a doctorate from Hamburg University (Germany, '91) and a Master's degree from Harvard School of Public Health ('97). Since 2006, he has been Director of Clinical Research in Newborn Medicine at the Floating Hospital for Children at Tufts Medical Center. Since 2008, he also serves as Director of the Pediatric Clinical Research Center at the Floating Hospital.

Dr. Dammann is Research Professor of Pediatrics and Clinical Research at Tufts University School of Medicine and Wilhelm-Hirte-Professor of Perinatal ID Epidemiology at Hannover Medical School (Germany). His research is concerned with the etiology of perinatal brain damage and retinopathy of prematurity in preterm infants. He is co-investigator and member of the steering committee of the ELGAN study, funded by NIH with 21 million dollars to study molecular antecedents of white matter damage in preterm newborns. He is currently funded by NIH (NEI) to perform ancillary analyses in the ELGAN database to identify placenta characteristics that might help predict the risk for retinopathy of prematurity. He is also the Principal Investigator of NEOBRAIN, a multinational consortium funded by the European Union with 3.5 million Euros to study neuroprotective strategies in preterm newborns. Dr. Dammann currently serves on the editorial boards of the pediatric scientific journals *Early Human Development*, *Neonatology*, and *Acta Paediatrica*. His bibliography lists more than 100 published papers.

Denise Hartnett Daudelin, RN, MPH

Ms. Daudelin, is an Investigator and Project Director at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center and Assistant Professor of Medicine at Tufts University School of Medicine. She is currently the Director of the Prehospital Stroke Quality Improvement Initiative sponsored by the Massachusetts Department of Public Health. Previously, she was the Project Director and Investigator for the EMS-Based TIPI-IS study, an AHRQ funded project using health information technology to measure and improve the care of patients with possible heart attacks in the prehospital setting. She was also the project director for the AHRQ sponsored patient safety project on using TIPI Systems to Reduce Errors in

Emergency Cardiac Care. Prior to joining the Institute, Ms. Daudelin was Director of Outcomes Analysis and Improvement at Tufts Medical Center, where she developed and implemented operational QI and patient safety programs, co-developed QI and Resource Utilization software, and worked with clinicians to evaluate incidents and causes of medical errors.

Barbara L. Gandek, MS

Ms. Gandek is currently Director of International Research & Development and a Senior Scientist at QualityMetric Incorporated, and an Instructor at the Tufts University School of Medicine. Previously she was a Scientist and Director at the Health Assessment Lab (1998-2008), Senior Project Director at The Health Institute at New England Medical Center (1989-2000), Project Manager and Consultant at the Health Data Institute (1983-1989) and Research Assistant at Mathematica Policy Research (1980-1982). She is a co-author on over 40 peer-reviewed articles on various aspects of PRO measurement and on eight manuals about the SF-36 Health Survey and other PRO measures. Much of her work since 1991 has been in the international field, and she co-edited (with Dr. John Ware) a 326-page special issue of the *Journal of Clinical Epidemiology* devoted to the work of the IQOLA Project, one of the earliest efforts to translate a PRO instrument across countries. In addition to her international work, she currently is Project Manager for QualityMetric on the Patient-Reported Outcomes Measurement Information System (PROMIS), a cooperative network that has been funded under the NIH Roadmap for Re-engineering the Clinical Research Enterprise to substantially improve the way patient-reported outcome measures are used in clinical research. Ms. Gandek has a Master's in Health Policy and Research from the Harvard School of Public Health and a Bachelor's with Honors in Economics from Swarthmore College.

Robert J. Goldberg, PhD

Dr. Goldberg, Adjunct Professor of Medicine, is Professor of Medicine and Epidemiology at the University of Massachusetts Medical School. Dr. Goldberg's research includes the study of the natural history of coronary heart disease, particularly with regard to examining changes over time in the incidence and survival rates of acute myocardial infarction and out-of-hospital coronary deaths. Dr. Goldberg is also involved in monitoring changing trends in the Central MA population in the magnitude, hospital and long-term outcomes, and management of patients with heart failure and venous thromboembolic disease.

Kathleen J. Goonan, MD

Dr. Goonan, Assistant Professor of Medicine, is a Senior Scientist in the Center for Health System Design and Evaluation at the Massachusetts General Hospital's Institute for Health Policy. She is the former Vice President of Health Affairs and Chief Medical Officer for Blue Cross Blue Shield of Massachusetts. Her research focuses on clinical quality management and incentives affecting physician practice patterns.

John L. Griffith, PhD

Dr. Griffith, founder of the Biostatistics Research Center (BRC), is Associate Professor of Medicine at Tufts University, holds a faculty appointment in the Sackler School, and is a member of the Special and Scientific Staff at Tufts Medical Center. He directs the Design and Data Resource

Center at Tufts Medical Center. Dr. Griffith is a Senior Statistician on a national project investigating factors that impact the pediatrician's level of suspicion of child abuse (RO1 HS10746). Dr. Griffith was the Principal Investigator for a grant comparing different modeling methods for prediction of medical outcomes (R01-LM05607), and for another grant developing and investigating appropriate statistical procedures for assessing predictive model performance (R03-HS09561). Dr. Griffith is currently Co-Principal Investigator for the Data Coordinating Center for the Immediate Trial, coordinates data cores for the Nutrition and Memory in the Elderly project, and the Puerto Rican Center on Health Disparities. Dr. Griffith teaches in the Clinical and Translational Science Graduate Program at the Sackler School of Graduate Biomedical Sciences, and is a member of the Faculty Advisory Committee. In addition, Dr. Griffith is the Statistical Editor for the journal *Clinical Infectious Disease*, a member of the Tufts Medical Center Scientific Review Committee (SRC), and the hospital's Institutional Review Board (IRB). He also serves on the Veterans Affairs Scientific Review and Evaluation Board. Dr. Griffith is also Co-PI of the newly awarded Tufts CTSA award, and Co-Director of the Tufts Clinical and Translational Research Institute Research Portal.

Judith A. Hinchey, MD

Dr. Hinchey is Assistant Professor of Neurology in the Department of Neurology at Caritas St. Elizabeth's Medical Center. She graduated from Tufts University School of Medicine and completed her training in Neurology at Tufts Medical Center. Subsequently, she completed a Neurophysiology fellowship at the Beth Israel Hospital in Boston prior to completing a cerebrovascular fellowship at The Cleveland Clinic. She received a Career Development Award from the National Institutes of Health to study the quality of care in cerebrovascular disease. Her focus is in developing models to predict stroke outcomes that could be used to compare hospitals or identify process of care measures to be implemented to improve patient outcome. She is particularly interested in studying the in-hospital care of stroke patients. She has recently completed a study sponsored by the American Academy of Neurology and the American Stroke Association. The study was of the stroke practice improvement network which tested whether audit, feedback and benchmarking were as good as audit, feedback, benchmarking and hospital specific barrier identification to improve the care of four quality measures in ischemic stroke. She is now the Quality Improvement Director for the Massachusetts-based Paul Coverdell National Acute Stroke Registry. The goal is to help hospitals in Massachusetts improve adherence to stroke specific in-hospital quality measures. Dr. Hinchey also serves as the Stroke Director for Caritas St. Elizabeth's Medical Center. Dr. Hinchey acts as a Project Mentor.

John P. A. Ioannidis, MD, PhD

Dr. Ioannidis is Professor and Chairman of the Department of Hygiene and Epidemiology at the University of Ioannina School of Medicine in Greece and Adjunct Professor of Medicine at Tufts. He received his medical degree at the University of Athens Medical School and earned a doctorate in Biopathology. He has authored over 350 peer-reviewed papers in high-impact journals and serves on the editorial board of 21 journals. His research interests include evidence-based medicine, clinical and molecular epidemiology, genetic epidemiology, meta-

analysis, mathematical modeling, clinical research methods, infectious diseases, and chronic diseases.

Stanley C. Ip, MD

Dr. Ip is Assistant Professor of Pediatrics and Medicine at Tufts University School of Medicine and Assistant CCES Director. He is a Physician-Methodologist and has served as lead clinical expert and first author of several AHRQ-sponsored evidence reports. Dr. Ip was the lead author of a report on the management of neonatal hyperbilirubinemia and served on the FDA advisory committee on the use of stannosporfin injection. Dr. Ip also led the evidence review, *Comparative effectiveness of management strategies for gastroesophageal reflux disease*, the first such review under the AHRQ Effective Healthcare Program. He has also assisted in reviewing evidence for the development of the American Academy of Orthopaedic Surgeons guideline. Dr. Ip has supervised two AHRQ evidence review projects for the United States Preventive Services Task Force to update the Task Force recommendations on breastfeeding and management of hyperbilirubinemia.

Bertrand L. Jaber, MD, MS

Dr. Jaber, Associate Professor of Medicine, Tufts University School of Medicine, received his medical degree from St. Joseph University, Beirut, Lebanon. Dr. Jaber completed a fellowship at Tufts Medical Center and graduated from Tufts University Sackler School of Graduate Biomedical Sciences Clinical and Translational Science Graduate Program. With clinical interests in hypertension, chronic kidney disease, kidney stones, kidney transplantation and dialysis, Dr. Jaber is affiliated with St. Elizabeth's Medical Center in Boston.

Kenneth I. Kaitin, PhD

Dr. Kaitin, Professor of Medicine, is the Director of the Tufts Center for the Study of Drug Development. Dr. Kaitin's research includes the study of national and global trends in pharmaceutical and biotechnology research, development, and regulation. A former President of the Drug Information Association, Dr. Kaitin is deeply involved in research, teaching, and writing on issues related to pharmaceutical regulation, public policy, and the drug development process.

Jerome P. Kassirer, MD

Dr. Kassirer, Distinguished Professor, is the Senior Assistant to the Dean at Tufts University School of Medicine, and Senior Research Scientist at Yale University School of Medicine. He served as the 38th Editor-in-Chief of the *New England Journal of Medicine (NEJM)* between 1991 and 1999 and has published numerous original research and clinical studies, textbook chapters and books on nephrology (in particular, acid-base equilibrium), medical decision-making, and the diagnostic process. As a clinician, editor, and researcher, he has promoted professionalism, ethical scientific conduct, patient involvement in decision-making, appropriate use of firearms, and reliable approaches to the assessment of the quality of health care.

David M. Kent, MD, CM, MS**Associate Program Director, Clinical and Translational Science Graduate Program**

Dr. Kent is Associate Professor of Medicine at Tufts University School of Medicine and Associate Director of Clinical and Translational Science Graduate Program at the Sackler School of Graduate Biomedical Sciences, Tufts University, and the Clinical Research Training Program and Fellowship at the Institute for Clinical Research and Health Policy Studies, Tufts Medical Center. The theme of Dr Kent's research is how the average results from trials and other studies may be misleading to doctors who treat individual patients. With his collaborators, he has developed a framework by which predictive modeling is used to explore treatment-effect heterogeneity in clinical trials across fundamental risk dimensions, rather than testing individual variables in a one-at-a-time fashion. As Principal Investigator (PI) or Co-PI, he has received 5 federal grants for work directly related to this theme, focusing on cardio- and cerebrovascular illnesses. Additionally, he is Director of the Center for Predictive Medicine Research of the Tufts Clinical and Translational Science Institute (CTSI), which is a platform for the collaborative dissemination of these methods to other domains. He also has extensive peer-review experience having served for four years on the Scientific Review Committee of Tufts Medical Center, and on grant review sections for NIH, the VA Cooperative Studies, Foundations and foreign governments. He is Associate Editor of the journal *Trials* and Deputy Editor of the *Journal of General Internal Medicine*. He currently sits on a number of national working groups on Comparative Effectiveness Research (CER), including the IOM's Clinical Effectiveness Research Innovation Collaborative (CER-IC, Methods Workgroup) and the CTSA Comparative Effectiveness Workgroup (CER Methods Workgroup). He teaches Study Design, Introduction to Clinical Care Research and Predictive Modeling of Health Outcomes.

Richard I. Kopelman, MD

Dr. Kopelman, Professor of Medicine, is Vice Chairman of Education and Director of the Medical House Staff Training Program at Tufts Medical Center. He has written and taught extensively on clinical problem solving including the reasoning and decision-making use of both qualitative and quantitative methods.

Manlik Kwong, BS

Manlik Kwong is an ECG Integration Engineer at Tufts Medical Center's Center for Cardiovascular Health Services Research involved with various clinical studies on cardiovascular disease and stroke. Mr. Kwong's primary interest is in ECG related algorithm design using heuristics and artificial intelligence methods and approaches and data visualization in 2D and 3D. During his 11 years with Tufts Medical Center, Mr. Kwong has also designed and implemented data collection and web-based clinical information systems for emergency department and emergency medical services environments. Prior to joining Tufts Medical Center, Mr. Kwong had been a lead software engineer with Hewlett-Packard's Cardiology Business Unit designing ECG algorithms for various non-invasive patient monitoring devices. Mr. Kwong has BSEE and BSCS degrees from Oregon State University and holds five US patents in various ECG algorithms and analysis techniques, high volume printing solution, and distributed analysis.

Joseph Lau, MD**Concentration Leader for Evidence-based Clinical Effectiveness Research**

Dr. Lau, Professor of Medicine and Professor of Clinical Research, is the Director of the Center for Clinical Evidence Synthesis and Director of the AHRQ Evidence-based Practice Center in the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, all of which provide excellent teaching and research opportunities for trainees. Internationally recognized as a leader in meta-analysis research, Dr. Lau has published numerous articles on the clinical applications of meta-analysis, methodological innovations, and critical assessment of current meta-analytic methods. He has also led teams of methodologists in assisting the development of many evidence-based clinical practice guidelines.

Mary Y. Lee, MD, MS

Dr. Lee is Associate Provost of Tufts University, and Professor of Medicine at Tufts University School of Medicine. Dr. Lee manages multidisciplinary educational initiatives spanning Tufts' undergraduate, graduate, and professional schools, particularly efforts that leverage the synergies between the schools' unique strengths in the health sciences and commitment to international service. In addition, Dr. Lee provides key academic leadership for the educational use of information technology; the University Library Council; and faculty development in conjunction with the University Committee on Teaching and Faculty Development and the Tufts University Center for the Enhancement of Learning and Teaching that provides faculty training and support across the University. In her prior role as Dean for Educational Affairs at Tufts University School of Medicine, Dr. Lee promoted forward-looking uses of educational technology in health sciences education for which she is internationally recognized, and for which she is a frequent guest professor. Dr. Lee was the recipient of the Tufts University Distinguished Faculty Award in 2006.

Debra Lerner, MS, PhD**Concentration Leader for Health Services and Outcomes Research**

Dr. Lerner is a Senior Research Scientist at The Health Institute, within the Institute for Clinical Research and Health Policy Studies, of the Tufts Medical Center and Director of its Program on Health, Work and Productivity. She is an Associate Professor of Medicine at the Tufts University School of Medicine and the Sackler School of Biomedical Sciences, and Health Services Research Concentration Leader for the Graduate Program in Clinical Research. Dr. Lerner is a national leader in research concerning the impact of chronic health problems in the workplace. She has served in an advisory capacity to a wide range of public and private sector organizations including the Institute of Medicine, Agency for Health Care Research and Quality, The National Institute of Mental Health, The Institute for Health and Productivity Management, The Washington Business Group on Health (now the National Business Group on Health) and many employers. She is a faculty member and sits on the Board of Directors of the Academy for Health and Productivity Management. Under her leadership, Dr. Lerner and her colleagues developed the Work Limitations Questionnaire (WLQ). The WLQ is a brief, self-administered questionnaire measuring the impact of chronic health problems on job performance and work productivity. The WLQ has been used in projects throughout the world and has become a standard of measurement. Dr. Lerner is Principal Investigator on several research projects

concerning chronic illness and employment. Most recently, she received grants from the CDC and the NIMH to test a new program aimed at preventing work productivity loss due to depression. Dr. Lerner earned her PhD in Sociology from Boston University, and MS degree in Health Planning and Administration from the University of Cincinnati.

Laurel K. Leslie, MD, MPH

Dr. Leslie is an Associate Professor of Medicine at Tufts University School of Medicine, with a primary appointment in the Department of Medicine and holds a secondary appointment in the Department of Pediatrics. She is an active faculty member in the Tufts University Sackler School of Graduate Biomedical Sciences. She is also the Director of the Program for Aligning Researchers and Communities for Health within the Tufts Clinical and Translational Science Institute (CTSI). Dr. Leslie's research interests focus on the identification and treatment of developmental and mental health needs of children and adolescents across the health, mental health, and school sectors. Specific areas of inquiry include the impact of guidelines and policy initiatives on youth service use and outcomes and collaborative models of care across sectors that incorporate the child and family as active participants in care.

Andrew S. Levey, MD

Dr. Levey, Professor of Medicine, is Chief of the Division of Nephrology. His research is mainly in the areas of epidemiology of chronic kidney disease and cardiovascular disease in chronic kidney disease, controlled trials to slow the progression of chronic kidney disease, clinical assessment of kidney function, assessment and improvement of outcomes in dialysis and transplantation, and clinical practice guideline development and implementation. Dr. Levey is currently Program Director for an NIDDK-funded clinical research training program, "Clinical Trials, Epidemiology and Outcomes Research in Nephrology" and Editor-in-Chief of the *American Journal of Kidney Diseases*.

Peter Lindenauer, MD

Dr. Lindenauer is Associate Professor of Medicine in the Clinical and Translational Science Graduate Program and Chief Medical Information Officer at Tufts affiliate Baystate Health Center in Springfield, MA where he focuses on the role of computerized physician order entry systems to improve quality and enhance safety, the development and implementation of clinical practice guidelines, and the improvement of perioperative care. Other research projects he focuses on include care of patients with chronic obstructive pulmonary disease, the relationship between volume, quality of care and outcome in surgery, the effectiveness of heparins in the prevention of venous thromboembolism, and the impact of hospitalists on both clinical and financial outcomes. Dr. Lindenauer delivers seminars and acts as both Program Mentor and Project Mentor.

Tanya Logvinenko, PhD

Dr. Logvinenko, member of the Biostatistics Research Center since 2007, is an Assistant Professor of Medicine at Tufts University and a member of the Special and Scientific Staff at Tufts Medical Center. She received her PhD in Statistics from Stanford University in 2003. Her primary research interest is Bioinformatics, and in particular, the development of methodology

for the preprocessing and analyses of genomic and proteomic microarray data. Her expertise and collaboration are in clinical and medical research including design of clinical studies, and analysis of clinical (longitudinal, survival etc.), biological (genomic and proteomic microarray) and epidemiological data. Currently she is involved in collaborations aiming to identify antigens associated with protection against *V.cholerae* and autoantigens present in recent onset diabetics.

John H. Mason, PhD

Dr. Mason, Assistant Professor of Medicine, is Director of Health Services Evaluation for Blue Cross Blue Shield of Massachusetts. He leads a staff of 21 managers and associates with responsibilities for Healthcare Effectiveness Data and Information Set Quality and Utilization reporting, outcome and program evaluation, analysis of quality indicators and for quality improvement initiatives, population and disease specific health status assessment, quantifying member satisfaction with providers, developing a transaction-based quality problem identification process, configuring quality incentives for PCP/risk arrangement contracts, and survey development.

Timothy E. McAlindon, MD, MPH

Dr. McAlindon, Professor of Medicine, is the Chief of Rheumatology at Tufts Medical Center. Dr. McAlindon's research focus is in the area of osteoarthritis, and he has published extensively on this subject. His research interests also focus on the feasibility and validity of using the Internet to conduct clinical trials and epidemiologic studies.

Kimberley A. McGuigan, PhD, MBA

Dr. McGuigan, PhD, MBA is currently Senior Director/Team Leader, Evidence-based Medicine/Health Technology Assessment (EBM/HTA) in Primary Care at Pfizer. Before joining Pfizer, Dr. McGuigan spent five years (1999-2004) at Medco (formerly Merck-Medco), one of the largest US pharmacy benefits managers (PBM). Reporting to the Chief Medical Officer, she was responsible for leading Health Information/Health Information Technology teams and a Health Services R&D team. She was at RAND, a public policy think tank, from 1988-1999 and received a RAND President's Award in 1998 for her work in health policy research, quality of cancer care, and prostate cancer patient outcomes. Her work at RAND focused on statistical and econometric modeling; psychometrics including instrument development and evaluation (quality of life, psychometric scaling); health services cost and utilization estimation using claims and survey data; and predictive modeling. Dr McGuigan holds a PhD from UCLA in Health Services sponsored by Fellowships from the National Cancer Institute and the Agency for Healthcare Research and Quality; an MBA from the University of Pennsylvania, Wharton School of Business; and an MS in Applied Biometry from University of Southern California Department of Preventive Medicine. Her list of publications includes articles in the *New England Journal of Medicine*, *JAMA*, *Journal of the National Cancer Institute*, *Health Affairs*, *Journal of Economics and Management Strategy*, and *Evaluation Review*, among others. She was elected Fellow of the American Statistical Association in 2004 for "exceptional leadership and service to the profession."

Catherine E. Milch, MD, MS

Dr. Milch received her medical degree from SUNY Stony Brook MD followed by a residency in Internal Medicine at Tufts Medical Center and a General Medicine practice in GMA. She completed a clinical research fellowship at the Tufts Medical Center Institute for Clinical Research and Health Policy Studies. Additionally, Dr. Milch earned a MS in Clinical Research from the Tufts University Sackler School of Graduate Biomedical Sciences. She is the recipient of several national grants, including from AHRQ and American Heart Association, to conduct research in modeling of diagnostic testing accuracy, medical errors, and primary care interventions for smoking cessation. Dr. Milch is currently a Medical Director in clinical research at a Boston-area pharmaceutical company helping to develop new drugs for patients with inflammatory diseases and cancer.

Peter J. Neumann, ScD**Associate Program Director, Clinical and Translational Science Graduate Program**

Dr. Neumann is Director of the Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, and Professor of Medicine at Tufts University School of Medicine. Prior to joining Tufts, he was on the faculty of the Harvard School of Public Health for ten years, most recently as Associate Professor of Policy and Decision Sciences. His research focuses on the role of cost-effectiveness analysis and risk-benefit tradeoffs in health care decision making. He has conducted numerous economic evaluations of medical technologies, including evaluations of treatments for Alzheimer's disease. He also directs a project to develop a comprehensive registry of cost-effectiveness analyses in health care. Dr. Neumann has contributed to the literature on the use of willingness to pay and quality-adjusted life years (QALYs) in valuing health benefits. His other research has focused on the Food and Drug Administration's regulation of health economic information, and the role of clinical and economic evidence in informing public and private sector health care decisions, including those made by the Medicare program. He is the author or co-author of over 100 papers in the medical literature, and the author of *Using Cost-Effectiveness Analysis to Improve Health Care* (Oxford University Press, 2005). He is a contributing editor of *Health Affairs* and member of the editorial board of *Value in Health*. Dr. Neumann has served as President of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and as a trustee of the Society for Medical Decision Making. He has also held various policy positions in Washington, including Special Assistant to the Administrator at the Health Care Financing Administration. He received his doctorate in health policy and management from Harvard University. Dr. Neumann is also the Associate Program Director for External Education Programs.

Susan K. Parsons, MD, MRP

Dr. Parsons is the Director of The Health Institute and its Center on Child and Family Outcomes within the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center. She is also a Professor of Medicine and Pediatrics at the Tufts University School of Medicine and at the Sackler School of Graduate Biomedical Sciences. Dr. Parsons is the Director of Novel Methods and Pilot Studies Component of the Tufts CTSI and Director of the Tufts Cancer Center's Measurement, Outcomes, and Biostatistics Program. She is Chair of the institution's

Scientific Review Committee. As a Pediatric Hematologist/Oncologist and Health Services Researcher, Dr. Parsons' primary research interests include: assessment of quality of life, functional impact, and fiscal impact of chronic illness on children and their families; instrument and methodological design and interpretation; and formal mentoring of health professionals. Dr. Parsons has participated in the development and formal evaluation of quality of life instruments designed for children with cancer, including the Child Health Ratings Inventories-General Module and HSCT Module (for pediatric bone marrow transplant recipients) and the Quality of Life Assessment (QUOLA, for children with brain tumors). These instruments are currently in use in national clinical trials. Dr. Parsons received a BA from Kirkland College, an MRP in health economics and planning from Cornell University, and an MD degree from Columbia University's College of Physicians and Surgeons. She completed residency training in pediatrics at Children's Hospital Boston and fellowship training in pediatric hematology/oncology at the Dana-Farber Cancer Institute. Since her move to Tufts Medical Center in 2003, she has continued to provide outpatient care to long-term survivors of pediatric cancers and HSCT.

Stephen G. Pauker, MD

Dr. Pauker, Professor of Medicine and a member of the Division of Clinical Decision Making, Informatics and Telemedicine at Tufts Medical Center, is internationally recognized for his contributions to the application of decision analysis to clinical problems, cost-effectiveness and cost-benefit analyses to health care policy, and medical/clinical informatics. His current interests include health policy and guidelines for cardiac disease and genetic testing, utility acquisition and comparison of health status measurement, expert systems for decision support in cardiovascular disease, inference and support of individual patient's decisions in genetics, neonatal screening programs, and decision analysis software.

Jessica Paulus, ScD

Dr. Paulus is an Assistant Professor of Medicine at Tufts University and an Instructor of Epidemiology at the Harvard School of Public Health. She joined the Design and Data Resource Center at the Tufts CTSI as an Epidemiologist and Associate Director in 2009. Dr. Paulus received her ScD from the Harvard School of Public Health in Epidemiology in 2008 and a BS from Haverford College in Molecular and Cellular Biology in 1999. Her primary research is focused on reproductive and genetic predictors of lung cancer risk and survival in women using a case-control study initiated at Massachusetts General Hospital. She also collaborates with researchers at the Tufts Cancer Center on translational studies of colon and hematologic cancer survival, and investigators from HSPH on a large scale cohort study of non-communicable disease in Africa. Dr. Paulus is interested in the implementation of novel teaching methods in public health and clinical research curricula, and teaches courses in epidemiologic methods in the Clinical and Translational Science Program at the Sackler School of Graduate Biomedical Sciences at Tufts University, Harvard Medical School and the Harvard School of Public Health.

Brian J. G. Pereira, MD

Dr. Pereira joined Advanced Magnetics as President in November 2005 and was appointed CEO in November 2006. Prior to joining Advanced Magnetics, he was President and CEO of New

England Health Care Foundation at Tufts Medical Center from 2001 to 2005 and has held various other positions at the Medical Center since 1993. A nationally-recognized expert on kidney disease and nephrology, Dr. Pereira has served on the editorial board of twelve scientific journals, is the Editor of the widely read textbook, "Chronic Kidney Disease, Dialysis and Transplantation," and has over 200 scientific papers to his credit. He is Professor of Medicine at Tufts University School of Medicine and the Sackler School of Biomedical Sciences. He also serves as a director of the National Kidney Foundation, Aksys, Inc., Kidney Care Partners, Satellite Health Care Inc. and Wellbound Inc. Dr. Pereira's work focuses on kidney disease, clinical outcomes and economics of healthcare.

Anastassios G. Pittas, MD, MS

Dr. Pittas is an Associate Professor of Medicine at Tufts University School of Medicine, an Adjunct Associate Professor of Nutrition and Policy at Tufts University Friedman School of Nutrition, Science and Policy and a Center Scientist at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. He received his BS degree from Massachusetts Institute of Technology and his MD degree from Cornell University Medical College. After completing his Internal Medicine Residency at the New York Presbyterian Hospital, NY and his Fellowship in Endocrinology at Tufts Medical Center, he joined the staff in the Division of Endocrinology, Diabetes and Metabolism at Tufts Medical Center where he has been active in all three areas of academic medicine, clinical care, research and teaching as they relate to the prevention and treatment of diabetes mellitus. Dr. Pittas serves as the Co-Director of the Dr. Gerald J. and Dorothy R. Friedman New York Foundation for Medical Research Diabetes Self-Education Program and as the Associate Director of the Endocrinology Fellowship Program. He is also the Director of the Endocrine Pathophysiology course at Tufts University School of Medicine. Dr. Pittas earned his MS degree in Clinical Research from Tufts University Sackler School of Graduate Biomedical Sciences in 2006. He is Diplomate of the American Board in Endocrinology and Metabolism. Dr. Pittas' research work on the role of vitamin D and calcium in cardiometabolic disease is supported by the National Institutes of Health (NIDDK and ODS) and the American Diabetes Association. His other interest is in Comparative Effectiveness Research (CER) as it relates to the care of patients with diabetes. He has co-authored over 50 publications including peer-reviewed journals, books, book chapters and evidence-based reports. Dr. Pittas has been a peer-reviewer for NIH study sections, and for other international research foundations, including the Canadian Institutes of Health Research, UK Diabetes, Children's Medical Research Foundation (Australia) and Health Research Council of New Zealand. He has also been a peer reviewer for major medical journals including *Annals of Internal Medicine*, *Archives of Internal Medicine*, *Lancet* and the *Canadian Medical Association Journal*. He is a member of various professional societies.

William H. Rogers, PhD

Dr. Rogers is Senior Research Scientist at The Health Institute in the Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, and Professor of Medicine, Tufts University School of Medicine. Dr. Rogers has over three decades of work applying statistical methods to studies of health and health care delivery. He served as Senior Statistician for both the Rand Health Insurance Experiment and the Medical Outcomes Study, two of the largest and

most methodologically complex health services research studies conducted. In addition, Dr. Rogers was a core team member of the Rand Prospective Payment Study that integrated chart reviews with HCFA administrative databases to study the effects of prospective payment on utilization and health outcomes. Since 1990, Dr. Rogers has worked in close collaboration with faculty of The Health Institute in the development, validation and application of measures to evaluate health care quality and the health of populations and to evaluate the outcomes of interventions designed to improve health care quality and health status. Dr. Rogers serves as the senior methodologist and technical advisor to numerous state, federal and private initiatives that are applying survey-based measures for purposes of monitoring and improving health care quality and health outcomes.

Michael B. Rothberg, MD

Dr. Rothberg received his MD in 1992 from New York University Medical Center. He completed an Internship and Residency at Mount Auburn Hospital in 1993 and 1995, respectively, and a Fellowship at Tufts Medical Center in 1999. Dr. Rothberg specializes in Internal Medicine at Baystate Medical Center in Springfield, MA.

Ronenn Roubenoff, MD

Dr. Roubenoff received his MD from Northwestern University in 1983, and trained in Internal Medicine and Rheumatology at the Johns Hopkins Hospital, where he was Chief Resident in Medicine (1986-87). In 1990 he completed concurrent fellowships in Rheumatology and in Clinical Epidemiology at Johns Hopkins, receiving a Master of Health Science degree. He then trained in Nutrition at Tufts University with Irwin Rosenberg, MD, and in Immunology with Charles Dinarello, MD. He was Chief of the Nutrition, Exercise Physiology, and Sarcopenia (NEPS) Laboratory from 1997 to 2002, and Director of Human Studies from 2001 to 2002, both at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. He is currently Adjunct Professor of Nutrition and Associate Professor of Medicine at Tufts University and Tufts Medical Center. From 2002-2006, Dr. Roubenoff was Senior Director of Molecular Medicine at Millennium Pharmaceuticals, Inc., in Cambridge, MA, where he directed research on biomarkers and personalized medicine. In January 2007 he became Sr. Director, Immunology Research and Development, at Biogen Idec, Inc., where he leads the Translational Medicine and Early Development efforts for the Immunology group. Dr. Roubenoff has done pioneering work on the interactions of nutrition, exercise and hormonal and immune regulators of metabolism in aging and chronic disease, including rheumatoid arthritis, osteoarthritis, and HIV infection. He is an internationally recognized authority on sarcopenia, translational medicine, and the use of biomarkers in drug development. He has published over two hundred papers in the medical literature as well as writing for lay audiences. He is co-author of a New York Times bestselling book on exercise and nutrition treatment of arthritis. Dr. Roubenoff has served on many NIH study sections, WHO committees, American Society for Nutrition Committees, Animal Care and Use and Institutional Review Committees, and as a reviewer for journals, foundations, and charities. He has won multiple awards, including membership in the Alpha Omega Alpha and Delta Omega honor societies; Fellow of the American College of Physicians and the American College of Rheumatology; the Robert H. Herman Memorial Award of the American Society for Nutrition; the American College of Rheumatology Senior Scholar

Award; Tufts University Distinguished Faculty Award; Teacher of the Year at Johns Hopkins Medical School; and the Oliver Smith Award for Extraordinary Service and Caring at Tufts Medical Center.

Robin Ruthazer, MPH

Ms. Ruthazer, member of the Biostatistics Research Center since 1995, is Assistant Professor of Medicine at Tufts University, and a member of the Special and Scientific Staff at Tufts Medical Center. As associate director for the Design and Data Resource Center at Tufts, she coordinates the statistical consulting service offered to clinical investigators at Tufts and affiliated hospitals. Ms. Ruthazer is a Statistician at the Center for Cardiovascular Health Services within the Institute for Clinical Research and Health Policy Studies. She is a statistical mentor to fellows in the Tufts University Sackler School of Graduate Biomedical Sciences, Clinical and Translational Science Graduate Program, and is actively involved in the data coordination centers of multiple ongoing clinical trials, and also collaborating on a variety of research projects with investigators in the Tufts Medical Center community. Ms. Ruthazer earned her Master of Public Health degree in biostatistics from The University of Michigan.

Dana Gelb Safran, ScD

Dr. Safran, until recently, was the Director of The Health Institute in the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center and Associate Professor in the Department of Medicine, Tufts University School of Medicine. Dr. Safran's empirical research has emphasized the measurement of primary care quality, and in particular, has focused on patients' experiences of care and outcomes. Over the last decade, she has led numerous state and national studies that examine differences in primary care performance under the leading models of health insurance in the United States and that identify the influence of doctor-patient relationship quality on outcomes. By providing detailed and rigorous measurement of the doctor-patient relationship, demonstrating its important influence on outcomes, and highlighting substantial performance differences under varying delivery systems, Dr. Safran's work has provided an important empirical basis for the drive to a more patient-centered health care system and toward the inclusion of patients' experiences as essential measures of health care quality. In addition, since 1998, Dr. Safran's national studies of Medicare beneficiaries' access to care, quality and health outcomes have contributed to policy discussions concerning the performance of Medicare HMOs and the debate about prescription drug coverage. She received her Doctor of Science degree in health policy from the Harvard School of Public Health. Dr. Safran was previously employed by the U.S. Congress Office of Technology Assessment and the United Hospital Fund.

Mark Sarnak, MD, MS

Dr. Sarnak is Associate Professor of Medicine of Tufts University, is Associate Director of Research Training in the Tufts Medical Center Division of Nephrology. A former graduate of the Tufts University Sackler School of Graduate Biomedical Sciences, Dr. Sarnak now is a member of the Program Advisory Committee and serves as both a Program and Project Mentor. His research covers a broad range of studies on cardiovascular disease and cardiovascular disease

risk factors in CKD. He is working on a series of projects relating cardiovascular disease and cardiovascular disease risk factors to the level of kidney function.

Christopher H. Schmid, PhD

Associate Program Director, Clinical and Translational Science Graduate Program

Dr. Schmid earned his PhD in statistics from Harvard University. He is a member of the Biostatistics Research Center since 1991, is a Professor of Medicine at Tufts University and a member of the Special and Scientific Staff at Tufts Medical Center. Dr. Schmid also holds a faculty appointment in the Sackler School of Graduate Biomedical Sciences at Tufts University where he directs the biostatistics/epidemiology concentration. Dr. Schmid's major research interests include the development and application of Bayesian models, statistical methods and computational tools for meta-analysis of diagnostic tests and clinical efficacy, methods for combining and analyzing multiple databases, and methods for handling missing time-dependent data in longitudinal studies. He is statistical editor for the *American Journal of Kidney Diseases*, and consults on a wide variety of clinical trials, cohort studies and on monitoring boards for government, industry, and academia.

Robert D. Sege, MD, PhD

Dr. Sege is Professor of Pediatrics, Boston University School of Medicine and Chief, Division of Ambulatory Pediatrics, Boston Medical Center. Prior to that, he was Professor of Pediatrics and Director of the Tufts Medical Center Pediatric and Adolescent Health Research Center and Director of Research for the Division of General Pediatrics. His research focus is in the area of adolescent peer violence and its prevention. His research provides expertise in community-based interventions and viewing intentional injury as a public health problem.

Harry P. Selker, MD, MSPH

Program Director, Clinical and Translational Science Graduate Program

Dean, Tufts Clinical and Translational Science Institute

Dr. Selker is Executive Director for the Institute for Clinical Research and Health Policy Studies, Chief of the Division of Clinical Care Research, Director of the Center for Cardiovascular Health Services Research at Tufts Medical Center and Dean, Tufts Clinical and Translational Science Institute. He is also Professor of Medicine at Tufts University School of Medicine and Director of the Clinical and Translational Science Graduate Program at the Tufts Sackler School of Graduate Biomedical Sciences. His clinical practice is in the Pratt Diagnostic Center at Tufts Medical Center. In his research, Dr. Selker studies the factors that affect clinical care and its outcomes, and develops treatment strategies, decision aids, and computer-based systems for improving care. He is known for a series of studies of the factors influencing emergency cardiac care, including clinical, socioeconomic and gender issues, and is particularly known for the development of cardiac "clinical predictive instruments." These decision aids provide emergency physicians with predictions of their patients' key outcomes for real-time use in clinical care. Two of these, the ACI-TIPI (acute cardiac ischemia time-insensitive predictive instrument) and TPI (thrombolytic predictive instrument), are in electrocardiographs in use world-wide. He also is known for the development of information systems that provide the results of the ACI-TIPI and TPI as feedback to improve clinical care. In addition, Dr. Selker's

research includes work on fundamental issues of clinical study design, data analysis, combination of clinical data, and computer-based mathematical models that predict clinical outcomes. Dr. Selker is also an active teacher and mentor of clinical researchers. His was the first of its kind MS/PhD graduate program in clinical research in a biomedical graduate school, and he has been involved nationally in the promotion of clinical research and clinical research training. He holds leadership roles in professional and scientific societies and serves on a variety of governmental and organizational committees and panels.

David R. Snyderman, MD

Concentration Leader for Clinical Investigation

Dr. Snyderman is Chief of the Division of Geographic Medicine and Infectious Diseases, Hospital Epidemiologist at Tufts Medical Center, and Professor of Medicine and Pathology at Tufts University School of Medicine. Dr. Snyderman has been involved in transplantation-related research for over 20 years. His research has focused predominantly on the role of Cytomegalovirus in solid organ transplantation. He developed Cytomegalovirus Immune Globulin, brought it to licensure, and was awarded a citation from the Massachusetts Department of Public Health for his efforts. He has been a Teaching and Research Scholar of the American College of Physicians. He was also awarded the Natalie V. and Milton O. Zucker prize from Tufts University School of Medicine for his research on viral infections in transplantation and was recently awarded the Ken Kaplan Clinician award from the Massachusetts Infectious Disease Society. In addition he has received a Distinguished Faculty Award from Tufts University School of Medicine. Current research interests include studies of probiotics, in which he is collaborating with Drs. Hibberd, Gorbach, and Goldin, as well as studies in transplant associated infections. His work is NIH supported.

Paul C. Stark, ScD

Dr. Stark is an Associate Professor and the Director of Statistics at Tufts University School of Dental Medicine and a former member of the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center. Dr. Stark received his doctorate from Harvard University. He has been involved with medical research in the Boston area since 1996. Dr. Stark is the instructor for several biostatistics courses at Tufts University. He also serves on the Scientific Advisory Committee for the Tufts Medical Center Clinical and Translational Research Center, as well as the Institutional Review Board. He is currently leading a research consortium of dental schools. His publications have included research conducted in the area of indoor bioaerosols; polycystic kidney disease, recurrent cardiovascular disease, glaucoma; Merkel Cell carcinoma; brachytherapy for early prostate cancer patients; anticoagulation in cancer patients with thromboembolic disease; chemotherapeutic response and survival in anaplastic oligodendrogliomas patients; survival in patients with gastrointestinal tract carcinoid tumors; and predictors of skeletal complications in metastatic breast cancer.

Norma C. Terrin, PhD

Dr. Terrin is Associate Professor at Tufts University School of Medicine and the Sackler School of Graduate Biomedical Sciences, Senior Statistician in the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, Director of Biostatistics in the Clinical and

Translational Research Center at Tufts, and Senior Statistician in the Data and Design Resource Center at Tufts. Dr. Terrin received her PhD in Mathematics from Boston University in 1990 and her BA from Sarah Lawrence College in 1976. She served on the faculty of the Department of Statistics at Carnegie Mellon University from 1989 to 1997, where she conducted research in applied and theoretical probability and statistical methodology, including work in time series analysis, stochastic process, fractional Brownian motion, and long memory processes, and taught probability and statistics for PhD, MS, and undergraduate students. Since coming to Tufts in 1996, her methodological research has included longitudinal analysis, meta-analysis, publication bias, predictive modeling, and model performance. Dr. Terrin collaborates with clinical and health services researchers in areas including pediatrics, nephrology, HIV-AIDS, pulmonary medicine, oncology, long term acute care, health plan evaluation, clinical care culture, health related quality of life, and health behavior. She teaches biostatistics and meta-analysis and mentors clinical research fellows. Dr. Terrin has received funding as Principal Investigator from the National Science Foundation (NSF) and the Agency for Healthcare Research and Quality (AHRQ). She has served on a study section for the AHRQ for four years, has reviewed for the NIH, and is Statistics Editor for Clinical Infectious Diseases.

Thomas A. Trikalinos, MD, PhD

Dr. Trikalinos is a physician by training and methodologist by profession. He received his PhD in genetic epidemiology from the University of Ioannina, Greece, in 2006. He has strong mathematical and methodological background and wide ranging research interests and collaborations. His research is on the methodology of all aspects of evidence synthesis, from systematic reviews to meta-analysis and decision modeling. In collaboration with prominent scientists in statistics and evidence-based medicine, Dr. Trikalinos has developed new statistical methodologies and conducted large scale empirical research. He is currently part of the Tufts team that develops Meta-Analyst, a piece of software that implements all common and many advanced meta-analysis methods, frequentist and Bayesian. Dr. Trikalinos has more than 50 peer-reviewed publications, has co-authored papers that have received well over 2000 citations and has an h-index of 19. He is a member of the editorial board of BMC Medical Research Methodology and Research Synthesis Methods.

James E. Udelson, MD

Dr. Udelson is Chief of the Division of Cardiology as well as Director of Nuclear Medicine at Tufts Medical Center/Tufts University School of Medicine in Boston. Dr. Udelson's research interests involve studying the effects of new therapeutic modalities in the setting of heart failure as well as chronic coronary artery disease, as well as studying the development of imaging modalities to assess those effects. He is an Associate Editor for the American Heart Association's cardiovascular journal *Circulation* since 2004, and was appointed as the initial Editor-in-Chief for the new journal *Circulation: Heart Failure* beginning in 2008. He is on the editorial board and has served as a Guest-Editor for the *Journal of the American College of Cardiology* and the *Journal of Nuclear Cardiology*, and has served on the AHA/ACC/ASNC Radionuclide Imaging Guidelines Writing Task Force. Dr. Udelson is Past-President of the 5,000+ member American Society of Nuclear Cardiology, and was recently elected to a 5-year term serving on the Board of Trustees of the 30,000+ member American College of Cardiology (ACC). He has chaired the

ACC's Cardiovascular Imaging Committee, served on the ACC Publications Committee, and is beginning a term as Chair of the ACC Governance Committee. He has served as a member of the FDA Medical Imaging Drugs Advisory Panel, is an invited advisor to the FDA's Division of Medical Imaging and Hematology Products, and has been invited as an ad hoc member of the FDA's Cardiovascular and Renal Drugs Advisory Panel. He is a member of the Association of University Cardiologists and the Association of Professors of Cardiology. He has been the recipient of several NIH grants for studies of the use of cardiac imaging to better understand the physiology of left ventricular function and to favorably influence clinical decision making. He has directed and/or participated in numerous clinical trials on heart failure and cardiac imaging, focusing on the role of new therapies and how they effect remodeling, physiology, function, and outcomes. Locally, he has been named several times by *Boston* magazines as one of Boston's Best Doctors in cardiology. He has been PI of several federally funded trials, including "Myocardial Viability and Left Ventricular Remodeling in the Occluded Artery Trial" (RO1 HL075456-01, ancillary study to the NHLBI funded Occluded Artery Trial [OAT] examining the influence of infarct zone viability by radionuclide techniques on post-MI left ventricular remodeling at 40 international sites), and "Left ventricular function Core Laboratory for the IMMEDIATE Trial" ancillary study to the IMMEDIATE Trial, assessing the effect of immediate glucose-insulin-potassium given in ambulances and Emergency Departments for acute coronary syndromes. He has also been Co-PI of the "Assessment of Sestamibi Imaging in Emergency Department Chest Pain Patients" (Agency for Health Care Policy and Research/DHHS RO1-HS090110-01), a seven center, 2,500 patient randomized trial of an ED strategy incorporating perfusion imaging compared to a standard strategy in chest pain patients with non-diagnostic ECG's.

Katrin Uhlig, MD, MS

Dr. Uhlig is Assistant Professor of Medicine at Tufts University School of Medicine, staff physician in the Division of Nephrology, Tufts Medical Center, and Director, Guideline Development, at the Tufts Center for Kidney Disease Guideline Development and Implementation. Areas of research and special interest include the development of evidence-based clinical practice guidelines, conduct of systematic reviews, critical literature appraisal, teaching and mentoring in evidence based medicine. She received her MD and Dr. Med. from Aachen University, Germany, and her MS in Clinical Research from the Tufts University Sackler School of Graduate Biomedical Sciences, Boston.

Christine A. Wanke, MD

Dr. Wanke, Professor of Medicine, Community Medicine and Family Medicine, is a member of the Tufts Medical Center Division of Geographic Medicine and Infectious Diseases. Dr. Wanke is Director of Clinical HIV Research at Tufts Medical Center and is PI of an associated T32 training grant based on the Institute for Clinical Research & Health Policy Studies Clinical Care Research/Health Services Research (ICRHPS CCR/HSR) Program. She is a Core Director for the Tufts-Brown Center for AIDS Research and of other related centers. She has an R01 from NHLBI to examine dyslipidemias and cardiovascular risks in HIV and is a collaborator on several other NIH funded clinical research grants in HIV with faculty on this training grant as well as projects in community health centers with a significant Hispanic population. Dr. Wanke has a K24

(Midcareer investigator award for patient oriented research) in HIV Clinical Research which provides support for her time for mentoring trainees. She has extensive experience in mentoring fellows in Clinical Research, having worked with more than 40 pre- and post-doctoral trainees in the last 20 years. Of these trainees, the vast majority are in academics. Dr. Wanke is a member of the Program Advisory Committee and serves as both a Program Mentor and a Project Mentor.

John E. Ware, Jr., PhD

Dr. Ware, Research Professor of Medicine at Tufts University School of Medicine, is the Chief Scientific Officer of QualityMetrics, Incorporated. He was the Director of the landmark Medical Outcomes Study, run by The Health Institute, and he is the developer of the SF-36 Health Survey and other tools widely used in monitoring outcomes for patients treated in different systems of care.

John B. Wong, MD

Dr. Wong, Professor of Medicine, is Chief of the Division of Clinical Decision Making, Informatics, and Telemedicine. Dr. Wong has focused on the application of decision analysis to medical issues to help patients, physicians, and policymakers choose among alternative tests, treatments or policies. Areas of interest include the diagnosis and treatment of heart disease, screening for cancer, management of chronic hepatitis C and hepatitis B, selection of organ transplant candidates, biologic therapies for rheumatoid arthritis, Crohn's disease and psoriatic arthritis, and HIV therapy.

Ellen M. Zane, MA

Ms. Zane is the President and Chief Executive Officer of Tufts Medical Center and the Floating Hospital for Children, the first woman to run the hospital in its 210-year history. Ms. Zane is also an Assistant Professor in the Department of Medicine, Division of Clinical Care Research at Tufts University School of Medicine. Previously, she held the position of Network President for Partners HealthCare System, Inc. responsible for the development of a provider network featuring the Massachusetts General Hospital and Brigham & Women's Hospital along with community-based physician groups and community hospitals within eastern Massachusetts. The network encompassed 5600 physicians and represented \$800+ million of managed care revenue. Prior to that, Ms. Zane was the Chief Executive Officer at Quincy Hospital in Quincy, Massachusetts. Quincy Hospital is a 290-bed acute care community, public hospital managed by HCA and then Quorum Health Resources. Prior to her position as CEO, she was Quincy Hospital's Chief Operating Officer. Before that, Ms. Zane was the Vice President for Professional Services at the Morton Hospital & Medical Center in Taunton, Massachusetts. Ms. Zane received her Bachelor of Arts degree from the George Washington University in Washington, DC in 1973 and her Master of Arts degree in 1975 from the Catholic University of America in Washington. She is currently a Director of Parexel International (NASDAQ-PRXL), a Director of Fiduciary Trust Company, and a Director of Century Capital Management. She is a Trustee of Northeastern University and a member of the Health Policy and Management Executive Council at the Harvard School of Public Health. Ms. Zane also is on the Board of

Overseers at the Tufts University School of Medicine and a member of the Board of the Massachusetts Hospital Association.