Clinical Sciences

Chair, Graduate Program
Milton Packer, M.D.

Degrees Offered
- Graduate Certificate
- Master of Science in Clinical Science

Faculty

Professors
- Ira Bernstein, Ph.D., Vanderbilt University, 1963
- Robert Haley, M.D., UT Southwestern Medical Center, 1986
- Linda Hynan, Ph.D., University of Illinois at Urbana-Champaign, 1993
- Milton Packer, M.D., Jefferson Medical College, 1973
- Joan S. Reisch, Ph.D., Southern Methodist University, 1974
- John Z. Sadler, M.D., Indiana University School of Medicine, 1980
- Robert D. Toto, M.D., University of Illinois at Chicago, 1977
- Keith Argenbright, M.D., Tulane University, 1984; M.M.M., Carnegie Mellon University, 2009

Associate Professor
- Blair Holbein, Ph.D., Vanderbilt University, 1981

Assistant Professor

Clinical Sciences Objectives

UT Southwestern has emerged as one of the leaders in the nationwide initiative to develop a true academic home for clinical and translational research and clinical investigators. As part of this initiative, the Clinical Sciences Graduate Program offers investigators a Graduate Certificate or Master of Science in Clinical Science (MSCS). The program is housed in the UT Southwestern Graduate School of Biomedical Sciences.

The Education and Career Development Program involves trainees in a unique and rigorous multidisciplinary experience that will prepare them to become leaders of the next generation of clinical and translational investigators.

The comprehensive didactic curriculum is led by a multidisciplinary group of instructors that includes statisticians, epidemiologists, ethicists, experts in clinical research design and methodology, and other experienced clinical scientists. The curriculum provides instruction and reinforcement in the various aspects of clinical science. In addition to offering valuable knowledge and skills required to conduct clinical research, successful completion of the advanced-level training should assist individuals in becoming more competitive in seeking independent research support for clinical studies.

The vision is to enable the training of and launch the careers of predoctoral-, doctoral-, and postdoctoral-level students across all disciplines and Clinical and Translational Science Award (CTSA) partner institutions in Texas. The CTSA and Clinical Sciences Graduate Program provide outstanding education and career development training and resources that meet the trainees’ short-, intermediate-, and long-term clinical and translational science educational needs.

Facilities

The Program holds classes and seminars in medical school classrooms located on UT Southwestern’s South Campus, which is within walking distance of major hospitals and clinics. The program offers a flexible environment and sets achievable goals and expectations for busy clinical investigators who need to balance course work, research, patients, and their personal lives.

Requirements for Admission

The Clinical Sciences Graduate Program exists for predoctoral and postdoctoral candidates whose career goals include a heavy time commitment to conducting high-quality clinical research in an academic medical center.

All Candidates Must:

1. Fulfill all requirements for admission to UT Southwestern Graduate School of Biomedical Sciences.
2. Have a doctoral degree in biomedical science (e.g., M.D., Ph.D., Pharm.D., D.D.S., etc.) unless applying to the predoctoral track.
3. Have a current, formal affiliation with UT Southwestern or one of its partnering institutions.
4. Have a minimum of 75 percent protected time devoted to the didactic and Socratic curriculum, research project, and the research practicum. (50 percent for surgical/procedural subspecialties or graduate certificate students.)

5. Submit the following essays:
   - A career development plan.
   - A personal statement answering the following questions:
     - How did you arrive at this place in your career?
     - A career in clinical/translational research is challenging, with many opportunities and frustrations. Why are you attracted to this career?
   - A description of a potential research project.

6. Submit a current CV, using the standardized UT Southwestern Promotion and Tenure format.

7. Submit the four following letters of recommendation:
   - A detailed letter of support from the applicant’s Department Chair, guaranteeing 75 percent protected time for the master’s degree candidate for a minimum of two years (50 percent for trainees from Surgical and Procedural Programs and certificate students) and funding for the candidate’s salary and fringes during this time.
   - Two letters of reference from persons who can attest to the applicant’s professional or academic qualifications. Department Chair and Mentors should NOT be included on this list.
   - A letter from the applicant’s Scientific Mentor, documenting the applicant’s commitment to a career in clinical/translational research.

Curriculum

The curriculum is well suited for candidates who possess both a working knowledge of clinical medicine and excellent scholastic aptitude. Both the certificate and master’s degree Programs are designed to be completed in two to three years, depending on the amount of time the individual can commit to the didactic curriculum. Program requirements are tailored to meet the individual academic needs of each candidate by
the Program adviser. Required course work may include didactic courses in basic biostatistics, epidemiology, clinical research design, translational research, molecular genetics, grant-writing skills, and data analysis and management. Also, students may take courses from other area institutions that have similar clinical research or public-health programs, with prior permission of the Clinical Sciences Graduate Program Director.

**GRADUATE CERTIFICATE**

**DIDACTIC CURRICULUM:** 18 hours

**SOCRATIC CURRICULUM:** Active participation and regular attendance at seminars, lectures, grand rounds, visiting professorships, etc.

**RESEARCH PRACTICUM:** 6 hours

**MASTERS’ DEGREE**

**DIDACTIC CURRICULUM:** 20-27 hours, depending on specific track within master’s degree Program

**SOCRATIC CURRICULUM:** Active participation and regular attendance at seminars, lectures, grand rounds, visiting professorships, etc.

**RESEARCH PRACTICUM:** 9-18 hours, depending on specific track within master’s degree Program

**Course Descriptions**

**DIDACTIC CURRICULUM**

**5101 BIOSTATISTICS LABORATORY I**
Coordinates with and supports Conceptual Biostatistics for the Clinical Investigator and Mathematical Biostatistics for the Clinical Investigator. In this lab, students are introduced to biostatistics and the basics of management as well as grants and contracts from research foundations, advocacy organizations, and industry. How to write a persuasive, well-reasoned application will be the main focus of the course, including the budget, resources and environment, preliminary data, and the research plan. [SUMMER] (1 credit hour)

**5102 BIOSTATISTICS LABORATORY II**
Computer lab designed to carry out statistical analyses on commonly encountered experimental designs, using actual data. Extensive instruction in the use of commercially available statistical software packages is included. [SPRING] (1 credit hour)

**Prerequisite:** Concurrent enrollment in DCS 5391 or DCS 5101.

**5103 CLINICAL RESEARCH QUESTIONS AND METHODS**
This course covers defining and developing a research question; distinguishing between correlative and mechanistic questions; matching methods to questions; understanding bias and confounding, random, and systemic error; quantifying clinical information. [SUMMER] (1 credit hour)

**5105 ETHICS IN CLINICAL SCIENCE**
Introduction to ethical reasoning and related processes, techniques of settling disagreements among people, treatment versus research, informed consent, research relevant to third parties, dealing with unexpected scientific and clinically important findings, getting what you want from mentors, consent and risk issues with unproven biological markers, conflicts of interest/duty, handling misconduct and fraud, ethics of subject recruitment, compensating for injuries or medical errors in research, talking to media, public policy advising, authorship order and publication, gender and ethnicity in sciences careers. [FALL, SPRING, SUMMER] (1 credit hour)

**5106 GRANT WRITING AND FUNDING STRATEGIES**
This course will review the different types of federal grant mechanisms as well as grants or contracts from research foundations, advocacy organizations, and industry. How to write a persuasive, well-reasoned application will be the main focus of the course, including the budget, resources and environment, preliminary data, and the research plan. [SUMMER] (1 credit hour)

**5107 RESPONSIBLE CONDUCT OF RESEARCH**
This course examines regulatory requirements of clinical research (IRB, GCP, HIPAA, and investigational filings); ensuring patient safety; interactions with government and industry; contract negotiations; successful strategies and tactics. [SUMMER] (1 credit hour)

**5112 CLINICAL RESEARCH PROTOCOL DEVELOPMENT**
Practical aspects of research protocol conceptualization and development are examined. Enrollees have the opportunity to learn how to translate a research question into a hypothesis; how to identify and describe hypothesis-appropriate study subjects and study measurements; select a specific study design appropriate to the research question and resources available; synthesize the elements into a study plan; and develop a statistical section and analytical plan. Protocols developed by enrollees form the primary basis for group discussions. [SPRING] (1 credit hour)

**5115 CLINICAL RESEARCH FROM PROPOSAL TO IMPLEMENTATION**
Basic elements of a research proposal and implementation are covered. Topics include regulatory approvals; continuing regulatory oversight; monitoring patient safety; recruitment; clinical assessments; data treatment; data collection, entry, and auditing; provision of experimental tests/tasks; data analyses; publication planning. [FALL] (1 credit hour)

**5116 CLINICAL RESEARCH FROM PROPOSAL TO IMPLEMENTATION**
Basic elements of a research proposal and implementation are covered. Topics include regulatory approvals; continuing regulatory oversight; monitoring patient safety; recruitment; clinical assessments; data treatment; data collection, entry, and auditing; provision of experimental tests/tasks; data analyses; publication planning. [FALL] (1 credit hour)

**5201 DEVELOPING AND VALIDATING MEASURES**
This course concerns principles of creating, evaluating, and validating instruments and scales for the quantification of human responses and clinical events and the influence and interaction of physiological and behavioral factors. Students will engage in some data analysis so that they can better interact with psychometric specialists. Much of this course necessarily deals with statistics, but the stress is on practical considerations of constructing measures. Emphasis is given to what is generally known as “quality of life” measures. Much of the course involves the basics of factor analysis, which is essential to the analysis of scales. [FALL] (2 credit hours)

**5203 CLINICAL PHARMACOLOGY AND DRUG DEVELOPMENT**
Included are pharmacokinetics; pharmacodynamics; drug absorption, distribution, metabolism, and elimination; drug-drug and drug-disease interactions; preclinical drug development (Phase I, II, III, and IV); proof-of-concept and dose-finding studies; post-marketing surveillance. [SPRING] (2 credit hours)

**5207 OUTCOMES & HEALTH SERVICES RESEARCH**
This course covers the methods used in outcomes and health services research, which include research design, theory, measurement, methods of analysis, and evaluation of published research. Course objectives are to: 1) Describe basic concepts, definitions, and types of outcomes and health services research; 2) Understand structure, process, outcomes, and underuse, misuse, or overuse of conceptual models; 3) Identify common approaches and challenges in measuring cost, quality, access, and equity in health and health care; 4) Describe experimental and observational research designs used to assess the impact of health services (drugs, devices, procedures, strategies, delivery, and financing systems) on patient-oriented, clinical, and resource-use outcomes. [SPRING] (2 credit hours)

**5208 CLINICAL RESEARCH MANAGEMENT AND LEADERSHIP**
This course is a structured review and discussion of the basics of management and leadership theory and practice. Topics include project management and budgeting, information systems, leadership style, effective interviewing and hiring techniques, conflict resolution, and the basics of organizational culture. Predominant theories and research, as well as shared experiences of the instructor and the group, are discussed in order to enhance each participant’s effectiveness as a manager and leader. Several hours are spent throughout the course understanding and analyzing federal and state health policy (current and proposed) and the implications for the independent researcher. The curriculum combines assigned readings, didactic lectures, active group discussion, a mid-term project, and a final examination. [SPRING] (2 credit hours)
5301 CLINICAL RESEARCH DESIGN AND ANALYSIS
This class presents basic and intermediate principles in research design; formulation of the research question; identifying primary and secondary hypotheses; use of control groups and pre-specified hypotheses; surrogate measurements; analysis of incomplete data; meaning of P values and confidence intervals; and identification of bias and flaws in study design. [FALL] (3 credit hours)

5302 BIOSTATISTICS FOR CLINICAL SCIENCE II
Topics to be considered are linear and logistic regression models (control of confounding and predictive models); categorical data analysis (binomial and Poisson distributions); analysis of paired categorical data; nonparametric methods for ordinal data; survival analysis (Kaplan-Meier curves, hazard functions, types of censoring, log-rank tests, and generalized Wilcoxon tests, Cox regression model). [SPRING] (3 credit hours)
Prerequisites: DCS 5101 and 5391

5307 EPIDEMIOLOGY FOR THE CLINICAL INVESTIGATOR
This course offers considerations such as concepts of multivariate causality; criteria for establishing causality; risk; rates; incidence, prevalence, and attack rates; incidence density; crude, specific, and adjusted rates; relative risk, odds ratio, case-fatality rate and attributable risk; sampling error, selection bias, information bias, definition bias, and confounding; statistical techniques to control for bias; variables; overview of statistical analysis; multiple comparisons correction; study designs to avoid bias; survey and sample selection, cross-sectional, cohort, case-control; prospective versus retrospective; attributes of cohort studies; design principles of case-control studies; types of control groups; strategies of matching in case-control studies; experimental introduction to statistical computing for different types of clinical epidemiology studies. [SPRING] (3 credit hours)

5309 CONCEPTUAL BIOSTATISTICS FOR THE CLINICAL INVESTIGATOR
This course includes a conceptual approach to statistical analysis of biomedical data; review of fundamental statistical principles, focusing on explanation of the appropriate scientific interpretation of statistical tests rather than the mathematical calculation of the tests themselves. The course covers all topics typically used in biomedical publications (data description; summary statistics, p values, non-parametric tests, analysis of variance, correlation, regression, statistical power, and sample-size estimation).

5391 MATHEMATICAL BIOSTATISTICS FOR THE CLINICAL INVESTIGATOR I
The traditional mathematical approach to statistical analysis of biomedical data is examined. Topics include data description; elements of probability; distributions of random variables, including applications of the binomial and normal distributions; estimation and confidence intervals; hypothesis testing; analysis of variance; correlation and regression; and contingency tables. Additional topics include statistical power, sample size, and study design. [FALL] (3 credit hours)
Prerequisites: DCS 5101 and 5391

SOCRATIC CURRICULUM
The highly innovative Socratic curriculum complements the didactic curriculum. The Socratic curriculum consists of a rich selection of seminars and workshops, conducted using an interactive approach to provide continuous opportunities for clinical investigators to exchange ideas, apply knowledge, present and defend their work, critique the work of others, and participate in forums mimicking real-life conditions of peer review.

CLINICAL SCIENCE FORUM
Weekly presentations of research proposals to a peer group audience by early-career clinical investigators with lively critiques of substance and style by a panel of senior clinical investigators, with the intent of making key points of interest to all investigators.

DISTINGUISHED SPEAKER SERIES
Speakers of national and international stature allow intensive interactions with faculty members and clinical science trainees.

NEGOTIATION SKILLS WORKSHOP
This monthly workshop focuses on important issues for junior faculty, for example: negotiating for protected time, equipment, resources, promotion, and salary; achieving career milestones; surviving in academic medicine; and other career-building topics.

RESEARCH PRACTICUM
The Mentored Research Project is intended to be a hands-on training experience and should serve as an introduction to clinical or translational research practices. This training phase may involve the ongoing research projects of the scientific mentor, and the trainee will rely primarily on the resources already available for the ongoing research. The study may involve retrospective and/or prospective collection of data. In both retrospective and prospective studies, the trainee must be actively involved in the analysis of data, the preparation of presentations, and the writing of manuscripts. The trainee may also participate in the following activities: the development of protocols, the submission of IRB documents, the accrual of patients for prospective studies, etc. The trainee’s contributions to the project should be recognized by co-authorship (as appropriate) on abstracts, presentations, and manuscripts.

CRITICAL LITERATURE REVIEW
The trainee will write an original and critical review of the literature that synthesizes current knowledge and provides unique insights in a specific area of focus that will be career-establishing. The review should be thorough, analyzing and weighing the available evidence. The trainee is expected to critically review papers cited, identify strengths and weaknesses, and raise specific questions that need to be prospectively addressed in future research. These questions may form the basis for the Independent Research Project. Specifically, the review should:
1. Dissect the key papers with respect to strengths and weaknesses, synthesizing current knowledge in the field of study.
2. Clearly identify gaps of knowledge in that field.
3. Focus on what the trainee perceives as the current priorities for research in the field.
4. Include hypotheses and/or types of studies that would move the field forward, or propose research strategies that the trainee envisions will fill those gaps.

INDEPENDENT RESEARCH PROJECT
During the second and third years, the Clinical Scholar will carry out an Independent Research Project as the principal investigator overseeing a multidisciplinary research team. The team may include a biostatistician, data manager, research coordinator, collaborators, and consultants. Initial support for the Independent Research Project may be provided by resources available to all Clinical Scholars (through the Department of Clinical Sciences and UT-STAR) and specific financial resources allocated to each Scholar by his or her mentor(s) and department. Using these resources, the Scholar will carry out the research plan.

The study should examine an important clinical and/or translational question, and the goal is to obtain interpretable data that can advance the field. The project should include a hypothesis/specific aims, background/rationale, study design/methods, literature cited, importance to career plan, and a detailed budget and justification. The project must be prospectively planned with the Scholar clearly identified as the PI.

RESEARCH GRANT APPLICATION
As the capstone to the Program, the trainee will write a competitive and properly formatted extramural grant application (NIH K23, K08, or equivalent foundation grant, such as AHA; all others need to be approved by the Career Development Committee in advance). It is also acceptable to turn in an R award grant application. The grant application will be developed with the close advice and guidance of the trainee’s mentor(s). The plan proposed by the trainee will have all of the elements of a formal research grant application and will use standard NIH forms (or similar forms for foundation-based career development awards). The trainee’s Critical Literature Review may form the background and significance of the proposal; results from the Mentored Clinical Research Project and Independent Research Project may be used as preliminary results in the grant application.

CAREER DEVELOPMENT
MENTORING
The Education and Career Development Program highly values the mentor experience. Effective mentorship is a critical element in the process by which mentees achieve excellence in the design and management of clinical research, facilitating their growth as leaders in clinical and translational science. By the end of the first semester, the trainees must identify both a Scientific and Career/Humanistic mentor.

Mentors provide meaningful and invaluable guidance to trainees related to their career plans, including help with the selection of a mentored research project, research design, data collection, and analysis and feedback on written work (publications and grant applications). Mentors assist trainees in meeting personal and programmatic expectations and guide them toward independence and a successful career in academic medicine.

CAREER DEVELOPMENT COMMITTEE
The Career Development Committee is the Education and Career Development Program’s steering and oversight committee. This group establishes Program policies and processes, reviews student and mentor feedback and other training program evaluation data, reviews and develops courses, reviews and approves research practicum projects, and makes final decisions on degree completion. It has a fundamental role in the evaluation and continuous development and implementation of the Program.