2017 Center for Translational Medicine Clinical and Translational Research Scholars Program

Contact information: Amy Mackenroth, M.A., Supervisor of Education Programs
CTMeducation@UTSouthwestern.edu or 214.648.2752

Sponsored in part by a Clinical and Translational Science Award (CTSA) grant from the National Center for Advancing Translational Science (KL2TR001103, UL1TR001105)

Executive Summary: The Center for Translational Medicine (CTM) at the University of Texas Southwestern Medical Center (UTSW) invites competitive applications from junior faculty, fellows, and residents from UTSW and partner institutions to participate in the 2017, two-year CTM Clinical and Translational Research Scholars Program (Program). The Program is designed to provide intense research training and career development opportunities in a multidisciplinary setting that culminate in the submission of an extramural career development grant application (or equivalent). Candidates with research or health professional doctoral degrees and a strong commitment to clinical and/or translational research are eligible and encouraged to apply. These include junior faculty, clinical research fellows, and residents who have 75% protected time for research. Deliverables include a completed research project, a publishable manuscript, and an extramural grant application such as an NIH K award. Scholars will also acquire competence in critical thinking, team science, leadership, biomedical statistics and informatics.

Goal of the Program: The goal of the Program is to prepare junior investigators for a successful career in clinical and translational research. It is expected that scholars will initiate a team-based clinical and translational research program leading to successful acquisition of an extramural grant as a faculty member in an academic medical center. We aim to produce successful junior investigators in clinical and translational research by providing critical resources and support to launch their research career.

Program Highlights:

- **Two years long.** It is anticipated that scholars will obtain a Graduate Certificate in Clinical Science by completing the research practica projects and courses.*
- **Emphasizes a rigorous scientific approach.** The approach embodies our belief in hypothesis-driven, (especially but not exclusively) mechanistic-based investigation from the molecular to the population level.
- **Offers training in research skills.** The CTSA supports research training that spans the spectrum of clinical and translational science as envisioned by the National Center for Advancing Translational Science (Figure 1).
- **Develops critical thinking skills.** The Program is designed to enable trainees to lead teams that focus on significant translational problems. Critical thinking will be developed in the classroom using the Socratic Method, in small groups by giving oral presentations, and by written practica (Figure 2).
- **Fosters team science.** The Program recognizes the complexities of human research in the areas of genomic and molecular science require investigators to succeed through multidisciplinary scientific teams.
- **Offers mentorship and mentor training.** The Program aims to develop critical leadership, team building, and mentoring skills to equip our trainees and their mentors with the ability to navigate the clinical and translational research process and to communicate with groups of different scientific expertise.
- **Provides additional mentoring and leadership training for** former scholar alums’ transition to independence after completion of the two-year program.

*Scholars may choose to enroll in the Master of Science in Clinical Science program. Completion of the master’s degree may require additional coursework that extends beyond two years.*
Program Requirements:

- Two-year commitment at 75% protected time.
- Three written practica (Figure 2).
- Required courses*:
  - Responsible Conduct of Research
  - Clinical Research Management and Leadership
  - Grant Writing & Funding Strategies
  - Informatics for Clinicians and Clinical Investigators (online through UT Health Science Center Houston)
- Attend the two scheduled scholar retreats per year for the entire time, and present research at one retreat per year. Anticipated 2017-2018 dates: Friday, October 20, 2017 and Friday, March 30, 2018.
- Additional attendance requirements include:
  - \( \geq 50\% \) of weekly Translational Science Forum Works-in-Progress presentations, and present at one per year (Wednesdays 12-1 PM);
  - At least 3 of 4 quarterly program meetings (2nd Tuesdays, 12-1 PM – August, November, February, April).
- Active participation in ongoing group writing workshops, Center for Translational Medicine symposia, etc.
- Regular meetings with both the Scientific and Career/Humanistic mentors.

Mentorship Requirements:

Mentors should be actively involved in all areas of the program in order to best support the development of their mentee(s). Regular attendance at Translational Science Forum, Scholar Retreats, and other Socratic activities are expected. Mentors should have regularly scheduled meetings with their mentee(s). For more information, see the Mentoring Guidelines.

* Scholars may choose from a menu of elective courses. Scholars are expected to take additional courses customized to their career development plan as needed to increase research competency; subject areas such as biostatistics, epidemiology, informatics, health services research, quantitative methods, clinical research design, clinical research protocol development, ethics, as well as some basic science courses are available.

Program Deliverables:

- Three related practica:
  - A Clinical/Translational Research Project (chosen by the scholar and mentors)
  - A Publishable Manuscript (e.g., a Critical Literature Review, or scientific report)
  - An Extramural Research Grant Application such as a K23, K08, R01, or R21; other grants may be acceptable but must be approved in advance

- Competencies:
  - Scientific writing skills
  - Networking with the research community
  - Clinical research questions and study design
  - Literature critique
  - Research protocol implementation
  - Statistical approaches
  - Responsible conduct of research
  - Team science
  - Biomedical informatics
  - Clinical research interactions
  - Scientific communication skills
  - Cultural diversity
  - Translational teamwork
  - Leadership skills
  - Cross disciplinary training
  - Community engagement

- Appreciation:
  - For new technologies and methods pertaining to the spectrum of clinical and translational research.
  - For ethical principles that influence the translation of research results into practice.
  - For methodological and analytical concepts necessary to design rigorous clinical/translational research.
  - For applying knowledge through research experiences that will contribute to future grant proposals.

- Opportunities: To work with a career and scientific mentoring team consisting of faculty members who are experts in career development and committed to the scholar’s success.

Nota bene: The CTM Clinical and Translational Research Scholar Program is not related to UT Southwestern Disease Oriented Clinical Scholars (DOCS) Program.

Updated: September 1, 2016
Eligibility: The CTM Clinical and Translational Research Scholar Program is designed to provide additional training and focused mentorship to achieve the research career goals of individuals of exceptional scholarship, aptitude and critical thinking skills. Persons who show great scientific promise and are committed to pursuing a rigorous research training and career development plan are invited to apply. Applicants from a wide range of academic disciplines and from diverse backgrounds including underrepresented minorities, disadvantaged, and disabled individuals are encouraged to apply.

Applicants must:

- Have explicit support and commitment from their Department Chair(s) or Center Director(s), to provide:
  - At least 75% protected time for two years – this commitment must be confirmed in writing;
  - Funding for the candidate’s salary and fringes during this time (to the extent not supported by the CTM (see below under Financial Support);
  - A faculty appointment after completion of the Program, for those who are enrolled in the Program as clinical trainees (residents and clinical fellows) and not yet as faculty.
- Be committed to participate in the Program in a focused, active manner for two years and devote 75% of time and effort to its completion.
- Be committed to a clinical and translational science research career.
- Be appointed as a resident, clinical research fellow or junior faculty at UT Southwestern or one of the CTSA’s partner institutions;
- Have a terminal research or health-professional doctoral degree (e.g., MD, DO, PhD, PharmD, DNP, among others).
- Have completed initial post-graduate professional training (e.g., internship for those with an M.D. degree) by the start of the program.
- Have a well-formulated clinical and/or translational research plan and preferably previous research experience.
- Not be, nor have been, a principal investigator on an R01, R29, or subproject of a Program Project (P01), Center (P50, P60, U54) or mentored career development (K-series) grants or other equivalent research project grant awards. R03 and R21 grants are permitted.
- Be a U.S. citizen or permanent resident. Individuals on temporary or student visas are not eligible for NIH funding.

Financial Support:

- The Program is supported by a NIH Clinical and Translational Science Award (CTSA) and UT Southwestern Medical Center (UTSW).
- Scholar salaries may be funded by the nominating Department/Center (including departments with other K training grants), by CTSA KL2 funds, or by CTM institutional funds.
- Award of KL2/institutional funds for salary support is for two years and is highly competitive. Scholars selected for KL2/institutional funding will receive 75% of their UT Southwestern institutional base salary (up to the NIH cap) for two years. Since support by KL2/institutional funds is not guaranteed at the time of application, the nominating Department/Center must commit to provide full salary support unless officially notified otherwise by the CTM.
- Limited research funds may be available for select scholars, based on the annual CTM budget allocation.
- Select Scholars will have limited travel funds to attend the Translational Science Meeting in Washington, DC (annually in April), based on the CTM budget allocation.
- Availability of service package grants to pay for statistical support services are provided for all scholars whether or not they are receiving salary support for the duration of the program.
- Tuition provided for didactic courses, except for trainees supported by other federal funds (e.g., institutional training grants such T32 or other K grants).
- Scholars receiving KL2 funds should be aware that two years of salary support on the KL2 count toward time spent on a K grant (i.e. if you receive a K23, then you will have two years less than the maximum years allowed on that funding mechanism).

Application Instructions and Submission Process:
The CTM office is located on South Campus in the 3rd floor of the McDermott Administration Building (B Building). Please contact Amy Mackenroth, M.A., Supervisor of Education Programs, at CTMeducation@utsouthwestern.edu or 214.648.2752 with specific application or selection process questions.
The application consists of the following:

1. A curriculum vitae in the standard UT Southwestern promotion & tenure format; please add grants and teaching information at the bottom of the CV;

2. A career development and training plan;
   a. 1000 words or less; should be single-spaced, .5 inch margins, 11 point Calibri font: Include current area(s) of research interest, current areas of clinical/translational investigation, a proposed training plan including information about additional training, what you hope to gain from the mentor experience, what courses you think will be the most beneficial to your success, and career goals.

3. A personal statement;
   a. 500 words or less; should be single-spaced, .5 inch margins, 11 point Calibri font: 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?

4. A description of the proposed research project;
   a. 500 words or less; should be single-spaced, .5 inch margins, 11 point Calibri font. Include citations as necessary.

5. 1 letter with statement of commitment (75% protected time) from the Department Chair(s) or Center Director(s); this letter should specifically state the Department/Center’s support in the event the salary support is not available to the applicant;

6. 1 letter of recommendation from a professional reference;

7. 1 letter of recommendation from the scientific mentor who will oversee the scholar’s research project;

8. An online application to the Graduate Certificate Program in Clinical Science at UT Southwestern Graduate School of Biomedical Sciences (must submit online between 10/2/16 and 12/15/2016 for summer admission).

The applicant should submit Items 1-4 to Ms. Amy Mackenroth. The authors of letters of recommendation (items 5-7) should address their letters to Dr. Robert D. Toto and submit their letters directly to Ms. Amy Mackenroth. Item 8 should be submitted by the applicant online (link to online application to the Graduate School; you may need to clear the cache on your browser to make the login screen work).

Competitive applicants will be invited for interviews and will be asked to give short oral presentations (10 minutes, video recorded).

Note: The Program Selection Committee will not consider incomplete or late applications. Applications will undergo administrative review and the committee will invite selected candidates for interviews.

Schedule for Application and Selection Process:
Call for applications issued: September 2016
Application due: December 1, 2016
Candidate presentations (10 minutes): Individual presentation between November 1 and December 15, 2016
Interviews: January 24, 2017 from 4-6:30pm
Mandatory orientation: May 2, 2017 from 4-7pm
Appointment start date: July 1, 2017
Program completion date: June 30, 2019

Appendices:
Figure 1: Spectrum of clinical/translational research supported by the Program
Figure 2: Typical timeline for KL2/Clinical & Translational Scholars
Mentor-Mentee Guidelines/Agreement
Course requirements and electives for KL2 Graduate Certificate
Course descriptions

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Fig. 1: Spectrum of clinical/translational research supported by the Program
(T= translational. T0 Basic science discovery; T1 translation to humans; T2 translation to patients; T3 translation into practice; T4 translation to population health.)

Fig. 2: Typical timeline for KL2/Clinical & Translational Scholars
The research project, manuscript, and grant application should focus on the same research question/project.
Background
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 mentee must identify both a scientific and career/humanistic mentors. Being a mentor is a responsibility and a privilege, as it enables one to work with the best and brightest of the next generation. Together, the mentee and mentors will form a relationship focused on mentee career development as a clinical/translational researcher.

Expectations of Scientific Mentors
- Primary responsibility for guiding mentees toward research independence. Together with the mentee, the scientific mentor will help identify investigators to serve on the mentoring team. The scientific mentor will provide the mentee with the scientific and methodological expertise for their research projects.
- Clearly delineate specific expectations of the substantive learning/research skills to be achieved.
- Primary responsibility for helping the mentee develop both hypotheses and research protocols; providing the initial "peer review" that helps validate the scientific merit of all proposals; helping the mentee to obtain appropriate interdisciplinary consultations; assisting with all phases of grant preparation; and the development of effective presentations and publications.
- Overseeing and approving all required practica – mentor must submit a “mentor approval form” for each practica submission.
  a. Research project
  b. Publishable manuscript with critical component
  c. Research grant application (extramural; K23 or equivalent)

Expectations of Career/Humanistic Mentors
- Develop with the mentee specific milestones and timelines for achieving career development goals; help mentee to develop his/her career identity.
- Assist mentee in navigating the culture of academic medicine.
- Encourage mentee to expand his/her professional network.
- Mentee/mentor can set expectations that meet their specific needs associated with “life” issues, concerns, and celebrations; provide guidance with particular issues specific to gender, race, etc.

Expectations of ALL Mentors & Mentees
- The mentee is ultimately responsible for initiating and maintaining the relationship with the mentor(s). The mentee has the right to change mentors if his/her research question changes and/or the mentoring relationships are not meeting expectations.
- Although the idea of team mentoring is good, the mentoring relationship should be ultimately handled solely by the immediate mentor and mentee (not delegated).
- A standard expectation is that mentors will develop a relationship with their mentee, be available/accessible, be an advocate, and be resourceful.
- Regular and frequent meetings are essential for success. Thus, the mentee should have regular meetings with at least one member of the mentoring team, in addition to meeting with the entire mentoring group at least once per quarter. The mentee should prepare a brief formal summary of meetings with the entire mentoring team.
- The mentee will request that his/her mentors attend seminars at which the mentee is presenting. Attendance is highly encouraged as well as an important aspect of the development and growth of all mentees seeking a career in clinical research.
- Mentors and the mentee should participate in (a) the Scholars retreats; (b) evaluations and assessments of the individual mentee and team mentoring relationships; and (c) intimate involvement in the execution of the mentee’s practica for the program.
- The mentee is required to meet every six months with the Center for Translational Medicine, Education & Career Development team members to assess the overall mentoring experience; mentors & mentees will have an open line of communication with Keith Argenbright, M.D., M.M.M. (Mentorship, Leadership, and Career Development Director for the Center for Translational Medicine) and Amy Mackenroth, M.A. (Supervisor of Education Programs).
### Required Courses for Clinical & Translational Research Scholars

<table>
<thead>
<tr>
<th>Course #</th>
<th>UTSW Courses/Practicum</th>
<th>Credit Hours</th>
<th>Semester</th>
<th>New Required for Scholar Graduate Certificate - 5.5 hours coursework; 15 hours practicum credit</th>
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<tbody>
<tr>
<td>CTM 5501</td>
<td>Practicum: Research Project</td>
<td>5</td>
<td>N/A</td>
<td>required</td>
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<tr>
<td>CTM 5402</td>
<td>Practicum: Publishable Manuscript</td>
<td>4</td>
<td>N/A</td>
<td>required</td>
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<tr>
<td>CTM 5603</td>
<td>Practicum: Extramural Research Grant Application</td>
<td>6</td>
<td>N/A</td>
<td>required</td>
</tr>
<tr>
<td>CTM 5107</td>
<td>Responsible Conduct of Research</td>
<td>1</td>
<td>Summer</td>
<td>required</td>
</tr>
<tr>
<td>CTM 5208</td>
<td>Clinical Research Management &amp; Leadership</td>
<td>2</td>
<td>Spring</td>
<td>required</td>
</tr>
<tr>
<td>CTM 5106</td>
<td>Grant Writing &amp; Funding Strategies</td>
<td>1</td>
<td>Summer</td>
<td>required</td>
</tr>
<tr>
<td>HI 5XXX</td>
<td>UT Health Science Center at Houston - Informatics for Clinicians and Clinical Investigators (Online)</td>
<td>1.5</td>
<td>Spring</td>
<td>required</td>
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<tr>
<td>CTM 5301</td>
<td>Clinical Research Design &amp; Analysis</td>
<td>3</td>
<td>Fall</td>
<td></td>
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<tr>
<td>CTM 5309/5391</td>
<td>Biostatistics I (Conceptual or Mathematical)</td>
<td>3</td>
<td>Fall</td>
<td></td>
</tr>
<tr>
<td>CTM 5116</td>
<td>Clinical Research Protocol Development</td>
<td>1</td>
<td>Spring</td>
<td></td>
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<tr>
<td>CTM 5103</td>
<td>Clinical Research Questions &amp; Methods</td>
<td>1</td>
<td>Summer</td>
<td></td>
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<tr>
<td>CTM 5105</td>
<td>Ethics in Clinical Research</td>
<td>1</td>
<td>Fall (Odd)</td>
<td></td>
</tr>
<tr>
<td>CTM 5302</td>
<td>Biostatistics II</td>
<td>3</td>
<td>Spring</td>
<td></td>
</tr>
<tr>
<td>CTM 5115</td>
<td>Clinical Research from Proposal to Implementation</td>
<td>1</td>
<td>Fall</td>
<td></td>
</tr>
<tr>
<td>CTM 5307</td>
<td>Epidemiology for the Clinical Investigator</td>
<td>3</td>
<td>Spring</td>
<td></td>
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<tr>
<td>CTM 5201</td>
<td>Developing &amp; Validating Measures</td>
<td>2</td>
<td>Fall</td>
<td></td>
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<tr>
<td>CTM 5203</td>
<td>Clinical Pharmacology &amp; Drug Development</td>
<td>2</td>
<td>Fall</td>
<td></td>
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<tr>
<td>CTM 5207</td>
<td>Intro to Patient Centered Outcomes Research &amp; Comparative Effectiveness Research</td>
<td>2</td>
<td>Spring</td>
<td>electives</td>
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<tr>
<td>CTM 5113</td>
<td>Advanced Clinical Research Design &amp; Analysis</td>
<td>1</td>
<td>Spring</td>
<td></td>
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<tr>
<td>CTM 5141</td>
<td>Advanced Genetics II: Human Genetics</td>
<td>1.5</td>
<td>Spring</td>
<td></td>
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<tr>
<td>CR 5301</td>
<td>Mechanisms of Drug Action</td>
<td>3</td>
<td>Spring</td>
<td></td>
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<tr>
<td>CTM 5114</td>
<td>Preparing a Journal Report (Scientific Writing Workshop)</td>
<td>1</td>
<td>TBD - New</td>
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<tr>
<td>CTM 5XXX</td>
<td>Successfully Obtaining an R (SOAR) Grant Writing Seminar</td>
<td>0.5</td>
<td>Fall</td>
<td></td>
</tr>
<tr>
<td>CTM 5XXX</td>
<td>Mentoring Excellence for Developing Leaders</td>
<td>1</td>
<td>Varies</td>
<td></td>
</tr>
<tr>
<td>CTM 5XXX</td>
<td>CTM Socratic Curriculum</td>
<td>2</td>
<td>Varies</td>
<td></td>
</tr>
<tr>
<td>CTM 5096</td>
<td>Independent Study</td>
<td>1-3</td>
<td>All</td>
<td></td>
</tr>
<tr>
<td>UT Health Science Center at Houston Courses in Public Health and Bioinformatics</td>
<td>Vary</td>
<td>Vary</td>
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### Center for Translational Medicine Course Offerings

<table>
<thead>
<tr>
<th>Course #</th>
<th>Course Name</th>
<th>Credit Hours</th>
<th>Course Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Summer Courses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTM 5106</td>
<td>Grant Writing &amp; Funding Strategies&lt;br&gt;&lt;span class=&quot;core&quot; title=&quot;CORE (Toto)&quot;&gt;CORE&lt;br&gt;(Toto)&lt;/span&gt;</td>
<td>1</td>
<td>2-Day intensive course. 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 focus of the course including the budget, resources and environment, preliminary data, and the research plan.</td>
</tr>
<tr>
<td>CTM 5107</td>
<td>Responsible Conduct of Research&lt;br&gt;&lt;span class=&quot;core&quot; title=&quot;CORE (Holbein)&quot;&gt;CORE&lt;br&gt;(Holbein)&lt;/span&gt;</td>
<td>1</td>
<td>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.</td>
</tr>
<tr>
<td>CTM 5XXX</td>
<td>CTM Socratic Curriculum&lt;br&gt;&lt;span class=&quot;varies&quot;&gt;(Varies)&lt;/span&gt;</td>
<td>2</td>
<td>Students will participate in seminars dedicated to their comprehensive understanding of clinical and translational research, careers in academic medicine, and other relevant professional development topics.</td>
</tr>
<tr>
<td><strong>Fall Courses</strong></td>
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<td></td>
</tr>
<tr>
<td>CTM 5105</td>
<td>Ethics in Clinical Science&lt;br&gt;&lt;span class=&quot;sadler&quot;&gt;(Sadler)&lt;/span&gt;&lt;br&gt;&lt;i&gt;Offered in odd numbered years only.&lt;/i&gt;</td>
<td>1</td>
<td>Introduction to ethical reasoning and related processes, techniques of settling disagreements among people, treatment versus research, informed consent, clinical 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 publications, gender and ethnicity in sciences careers.</td>
</tr>
<tr>
<td>CTM 5391</td>
<td>Mathematical Biostatistics for the Clinical Investigator&lt;br&gt;&lt;span class=&quot;core&quot; title=&quot;CORE (Reisch)&quot;&gt;CORE&lt;br&gt;(Reisch)&lt;/span&gt;</td>
<td>3</td>
<td>Traditional, mathematical approach to statistical analysis of biomedical data. Topics include data description, summary statistics, 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.</td>
</tr>
<tr>
<td>CTM 5309</td>
<td>Conceptual Biostatistics for the Clinical Investigator&lt;br&gt;&lt;span class=&quot;core&quot; title=&quot;CORE (Hynan)&quot;&gt;CORE&lt;br&gt;(Hynan)&lt;/span&gt;</td>
<td>3</td>
<td>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, including data description, summary statistics, p values, and non-parametric tests, analysis of variance, correlation, regression, and statistical power &amp; sample size estimation.</td>
</tr>
<tr>
<td>CTM 5301</td>
<td>Clinical Research Design &amp; Analysis&lt;br&gt;&lt;span class=&quot;core&quot; title=&quot;CORE (Jacobe/Wolf)&quot;&gt;CORE&lt;br&gt;(Jacobe/Wolf)&lt;/span&gt;</td>
<td>3</td>
<td>Basic and intermediate level principles in research design; formulation of the research question; identifying primary and secondary structures; use of control groups and pre-specified hypotheses; surrogate measurements; analysis of incomplete data; meaning of P values and confidence intervals; identification of bias and flaws in study design.</td>
</tr>
<tr>
<td>CTM 5115</td>
<td>Clinical Research from Proposal to Implementation&lt;br&gt;&lt;span class=&quot;toto&quot;&gt;(Toto)&lt;/span&gt;</td>
<td>1</td>
<td>This course reviews basic elements for a research proposal and implementation. 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.</td>
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### Spring Courses

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Credits</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTM 5XXX</td>
<td>Successfully Obtaining an R (SOAR) Grant Writing Seminar (Yin)</td>
<td>0.5</td>
<td>SOAR is designed to increase NIH R-type grant acquisition success rates in basic, translational, and clinical research. SOAR includes topics such as demystifying the grant writing process, grantsmanship, surviving the NIH study section review, writing tips and tricks, navigating NIH requirements, peer-review, etc.</td>
</tr>
<tr>
<td>CTM 5207</td>
<td>Introduction to Patient Centered Outcomes Research &amp; Comparative Effectiveness Research (Halm)</td>
<td>2</td>
<td>This course covers the methods used in outcomes and health services research, which includes research design, theory, measurement, methods of analysis and evaluation of published research. Course objectives are: 1) describe basic concepts, definitions, and types of outcomes and health services research; 2) understand structure, process, outcomes and underuse, misuse, overuse conceptual models; 3) identify common approaches and challenges to 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.</td>
</tr>
<tr>
<td>CTM 5302</td>
<td>Biostatistics for Clinical Sciences II (Reisch)</td>
<td>3</td>
<td>This course covers 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).</td>
</tr>
<tr>
<td>CTM 5209</td>
<td>Clinical Research Questions, Methods &amp; Protocol Development CORE (Jacobe/Wolf)</td>
<td>2</td>
<td>The foci of this course are 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. Practical aspects of research protocol conceptualization and development. Enrollees will 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; develop a statistical section and analytical plan. Protocols developed by the enrollees will form the primary basis for group discussions.</td>
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<tr>
<td>CTM 5307</td>
<td>Epidemiology for the Clinical Investigator (Haley)</td>
<td>3</td>
<td>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 vs. retrospective; attributes of cohort studies; design principles of case-control studies; types of control groups; strategies of matching in case-control studies; experiential introduction to statistical computing for different types of clinical epidemiology studies.</td>
</tr>
<tr>
<td>CTM 5208</td>
<td>Clinical Research Management &amp; Leadership CORE (Argenbright)</td>
<td>2</td>
<td>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 will be discussed in order to enhance each participant’s effectiveness as a manager and leader. It will be a combination of assigned readings, didactic lectures, active group discussion, a mid-term project and final examination.</td>
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<tr>
<td>Course Code</td>
<td>Course Title</td>
<td>Credits</td>
<td>Description</td>
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<tr>
<td>CTM 5141 / GD 5141</td>
<td>Advanced Genetics II: Human Genetics (Zinn)</td>
<td>1.5</td>
<td>This is a half semester course. The course introduces students to the conceptual basis of human genetics research. Some of the classes review basic principles of medical genetics, since many students do not have any prior exposure to this subject, but discussions emphasize research applications rather than clinical problems. Topics include discovering the molecular basis of Mendelian disorders and complex traits through molecular cytogenetics, genetic linkage, and candidate gene and genomewide association methods. Discussion of research papers drawn from the current literature is used to illustrate each of these approaches.</td>
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<tr>
<td>CR 5301</td>
<td>Mechanisms of Drug Action (TBD)</td>
<td>3</td>
<td>The course is designed to cover a broad range of topics from fundamental principles in drug action to commercial applications. Topics include: 1. Examining how drugs interact with their receptors to induce their effects. 2. Allosteric regulation, receptor desensitization and intracellular trafficking, and biophysical methods to analyze drug-receptor interactions. 3. Review how drugs enter, distribute and become eliminated from the body and the mathematical analysis of their pharmacokinetics, as well as the development of drug tolerance and dependence. 4. Learn the principles underlying the action of a few selected classes of drugs and receptors. The second half of the course deals with specialized topics, including drugs used in psychiatry and drugs of abuse, in the chemotherapy of bacterial and virus infections, and in the treatment of parasitic diseases and the problems of developing drugs for Third World countries. Topics include: drugs affecting cholesterol homeostasis, prostaglandins and leukotriene pharmaceuticals, the basis of drug interactions, and emerging cancer therapeutics (antibodies, RNA, DNA, gene therapy, nanoparticles). The final lecture concerns the process of drug development in the pharmaceutical industry and the scientific and commercial complexities of getting the drug from the laboratory to the bedside.</td>
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<tr>
<td>HI 5XXX</td>
<td>UT Health Science Center at Houston – Informatics for Clinicians and Clinical Investigators (Online); (Only available to matriculated CTM students.) CORE (Instructor Varies)</td>
<td>1.5</td>
<td>Train the next generation of clinical researchers in the basics of clinical information systems (CIS) so they can both use the data that is derived from these systems as well as understand the issues surrounding the design, development, implementation, and evaluation of CIS-based interventions. 1. Discuss the need for and integration of biomedical informatics and related tools used in clinical research. 2. Identify benefits and challenges of utilizing EHR data for clinical research. 3. Assess an i2b2 clinical data warehouse and determine whether it can be utilized for a specified clinical research question. 4. Utilize basic REDCap functionality for clinical research functions 5. Ascertain appropriate health data standards for a given purpose. 6. Describe challenges and considerations when using natural language processing in clinical research. 7. Recognize opportunities for enhancing clinical and translational research by incorporating bioinformatics. 8. Evaluate consumer and external informatics sources for appropriate use in clinical research.</td>
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<tr>
<td>Semester Varies</td>
<td>Preparing a Journal Report (TBD)</td>
<td>1</td>
<td>General writing skills and strategies; how to prepare an empirical article including tips on writing the abstract, introduction, aims, methods, results, and discussion/conclusion sections of a peer reviewed journal article. Students will be required to submit a journal article and review others’ articles.</td>
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<tr>
<td>CTM 5113</td>
<td>Advanced Clinical Research Design &amp; Analysis (TBD)</td>
<td>1</td>
<td>By the end of the course, students will be able to critically review and critique the methods of scientific journal articles pertinent to academic medicine.</td>
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<td>Course Code</td>
<td>Course Title and Details</td>
<td>Credit Hours</td>
<td>Description</td>
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<tr>
<td>CTM 5203</td>
<td>Clinical Pharmacology &amp; Drug Development (Holbein)</td>
<td>2</td>
<td>Pharmacokinetics; pharmacodynamics; drug absorption, distribution, metabolism/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.</td>
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<tr>
<td>CTM 5XXX</td>
<td>Mentoring Excellence for Developing Leaders (Argenbright)</td>
<td>1</td>
<td>This is an interactive, participant-based course on mentoring excellence. Its objective is to engage mentors at all points in their career and give them the tools and skills necessary in order to improve their mentoring. This course is based on a combination of mentoring curricula and techniques that were observed at high performing translational medical centers (UCSF, Harvard, Wisconsin) as well as the National Research Mentoring Network (NRMN) mentor training. The NRMN curriculum facilitates career-stage appropriate training for mentors and mentees, tailored to foster the success of a diverse group of biomedical researchers, with a specific focus on deepening the alignment and impact of mentoring relationships.</td>
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<tr>
<td>CTM 5096</td>
<td>Independent Study/Special Topics (Assigned mentor)</td>
<td>1-3</td>
<td>The independent study is a self-guided course designed for matriculated Center for Translational Medicine students to develop, in collaboration with a mentor, a special topics course directly related to their field of research. This tutorial-type course may cover a topic of your choice and should be directly related to your current research. The course is designed to be flexible with 1 credit hour given for every 15 hours of work and related research time. Maximum credit given is 3 credits/45 research and meeting hours. You must have at least three meetings per credit hour with your mentor who will guide you in this hands-on research opportunity.</td>
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</table>

**Other**

- Online courses offered through the University of Texas Health Science Center at Houston. (Only available to matriculated CTM students.)

  - **Courses offered through the School of Public Health in the division of Health Promotion & Behavioral Sciences**
  - **Courses offered through the School of Biomedical Informatics**