Responsible Conduct of Patient-Oriented Clinical Research

Patient-Oriented Clinical Research Methods

Patient-Oriented Clinical Research Biostatistics • Integrating Molecular Biology with Patient-Oriented Clinical Research • Data Management, Quality Control, and Regulatory Issues • Grantsmanship and Peer Review • Health Services Research • Instrument Validation and Development • Genetics and Genetic Epidemiology • Cross Cultural Grant of Research • Responsible Conduct of Patient-Oriented Clinical Research • Patient-Oriented Clinical Research • Instruments • Responsible Conduct of Patient-Oriented Clinical Research • Instruments • Responsible Conduct of Patient-Oriented Clinical Research • Instruments • Responsible Conduct of Patient-Oriented Clinical Research Clinical Research

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Instrument Validation and Development

Genetics and Genetic Epidemiology

Cross Cultural Adaptation of Research Instruments • Responsible Conduct of Patient-Oriented Clinical Research • Patient-Oriented Clinical Research Methods • Patient-Oriented Clinical Research Biostatistics • Integrating Molecular Biology with Patient-Oriented Clinical Research

Data Management, Quality Control, and Regulatory Issues

Grantsmanship and Peer Review

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Patient-Oriented Clinical Research Methods

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MSCI Program

IIMS/C-TREO – MC 7757 UT Health Science Center at San Antonio 7703 Floyd Curl Drive San Antonio, Texas 78229-3900 210-567-4631 (voice) 210-567-4301 (fax) E-mail: msci@uthscsa.edu

The UT Health Science Center at San Antonio is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools (1866 Southern Lane, Decatur, Georgia 30033-4097: Telephone number 404-679-4501) to award certificates, and baccalaureate, masters, doctoral, and professional degrees.

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Master of Science in Clinical Investigation (MSCI)

Program, Policies, and Guidelines

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THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO GRADUATE SCHOOL OF BIOMEDICAL SCIENCES

Master of Science in Clinical Investigation (MSCI)

AIMS/OBJECTIVES

The goal of this program is to prepare investigators skilled in the conduct of outstanding clinical and translational research in culturally diverse settings.

The specific aims of the MSCI Program are to:

- Support the intellectual environment at the UT Health Science Center at San Antonio for the optimal training of future clinical and translational investigators.
- Provide fundamental curricular activities and valuable training opportunities in clinical and translational research to UT Health Science Center at San Antonio students, postdoctoral trainees, and faculty from the Schools of Medicine, Nursing, Dentistry, Allied Health, and Graduate School of Biomedical Sciences (GSBS) as well as from local organizations that are partnered with UT Health Science Center at San Antonio.

The aims of the MSCI Program will be achieved via completion of objective activities:

- Participation and successful completion of required didactic coursework
- Establishment of an *approved* Supervising Professor, Supervising Committee and research project
- Active involvement in an approved research project
- Formal, semi-annual assessment of progress
- *Submission of an approved manuscript for peer-reviewed publication*
- Award of the Master of Science degree in Clinical Investigation (MSCI)

Admission Requirements

All students should have a sufficient educational background in the biological or biomedical sciences prior to admission to the program. It is expected that most students will have a health professional degree (*e.g.*, MD, DDS/DMD, or BS in nursing and/or allied health) or a BS/BA or MS degree with emphasis in a health-related discipline. The following general requirements will be applied:

- 1. A medical, dental, masters and/or baccalaureate **degree** from an accredited institution in the United States or proof of an equivalent degree and training at a foreign institution.
- 2. A grade point average (GPA) no lower than B (3.00 in a 4.00 system) in the last 60 hours of coursework for a BS/BA degree or a GPA of at least 3.0 for applicants with a MS degree.
- 3. A satisfactory score for the combined verbal and quantitative portions of the Graduate Record Examination (GRE). As recommended by the Graduate School of Biomedical Sciences (GSBS), a minimum of 1,000 for the combined scores on the verbal and quantitative portions of the Aptitude Test is desirable. Scores on GRE tests taken more than five years prior to the date of application are not acceptable. Applicants who have completed a graduate degree in a healthrelated discipline (MD, DDS, RN, or PhD) will be exempted from the requirement to complete the GRE.
- 4. A minimum score of 550 on the Test of English as a Foreign Language (**TOEFL**) for applicants from countries where English is not the native language. Scores on TOEFL tests taken more than two years prior to the date of matriculation are not acceptable.
- 5. Letters of recommendation (three) attesting to the applicant's readiness for graduate level studies in clinical investigation. These letters should be submitted with the online application to the GSBS. For residents or fellows in an approved UT Health Science Center at San Antonio residency or fellowship program, it is necessary to submit a letter from

the departmental Chairman with a statement indicating the availability and approval of release time for the completion of MSCI educational and research activities. Similarly, for UT Health Science Center at San Antonio staff, an authorized supervisor must provide a statement indicating the availability of release time for MSCI educational and research activities. Letters from Chairman (for residents or fellows) and/or from authorized supervisors (for staff) should be submitted either as a part of the online application or sent directly to the MSCI Academic Coordinator. The online application is available at:

http://apply.embark.com/grad/UTHSCSA/

- 6. A **Personal Statement** (1-2 pages) that includes a brief description of the applicant's background, long term research and career goals, and an indication of the basis for application into the MSCI Program including how this program fits into the applicant's career objectives. The Personal Statement should be submitted either with the on-line application to the GSBS or sent directly to the MSCI Academic Coordinator.
- 7. A **current curriculum vitae.** This should be submitted either with the on-line application to the GSBS or sent directly to the MSCI Academic Coordinator.

Applicants should utilize the <u>checklist</u> of required documentation for admission that is provided in the Appendix.

All of the **required** information described above **must** be submitted in order for an applicant to be considered by the MSCI Admissions Committee (see below). Requests for an exemption to any of these general admission requirements should be addressed to the MSCI Program Director and sent directly to the Academic Coordinator of the MSCI Program.

Academic Coordinator MSCI Program IIMS/C-TREO – MC 7757 UT Health Science Center at San Antonio 7703 Floyd Curl Drive San Antonio, Texas 78229-3900

Application to the MSCI Program

Application. An <u>online application</u> for admission into the MSCI Program must be processed through the UT Health Science Center at San Antonio Graduate School of Biomedical Sciences (GSBS). This application is available at:

http://apply.embark.com/grad/UTHSCSA/

As described in the online application for admission into the GSBS, official transcripts from **ALL** colleges and universities attended by the applicant are required; these must be submitted in sealed institutional envelopes. In addition, all transcripts from foreign institutions (including GPA) must be translated and submitted by an approved foreign credentialing evaluation agency. Official GRE and TOEFL test scores must also be submitted. For foreign nationals with a J-1 or H-1B visa, a copy of the visa must be submitted. And, F-1 visa holders must apply for and receive an I-20 form. For health care professionals, a copy of the applicant's medical license or other professional accreditation must also be submitted.

For all applicants:

- On-line application
- College/university transcripts (official)
- GRE scores (if non-MD or DDS)
- Letters of recommendation (3)
- Personal statement
- Curriculum vitae

In addition:

For Foreign Nationals:

- TOEFL scores
- Visa
- Supervising Professor, Supervising Committee, and research project

For Licensed Health Care Professionals:

• Medical license/certificate

Official test scores and transcripts should be sent to:

Registrar's Office-Graduate Admissions MSC 7702 The UT Health Science Center at San Antonio 7703 Floyd Curl Drive San Antonio, Texas 78229-3900

> gsprospect@uthscsa.edu Phone: 210-567-2667

Deadlines. The MSCI Program has an open application policy and will accept applications for admission at any time. However, *GSBS deadlines* (for submission of application and required documentation) for matriculation into a specific academic semester are listed below. **Applications for applicants intending to apply for or transfer a F-1 visa will only be accepted for consideration for matriculation in the Fall semester.**

- Fall Semester June 1
- Spring Semester October 1
- Summer Semester March 1

Applicants will have the responsibility for the timely submission of application materials to the MSCI Program in order to meet the deadlines established by the GSBS for registration and course enrollment.

Application Review. After receipt of the online application together with all of the required admission materials outlined above, the MSCI Admissions Committee will review and provide a recommendation to the MSCI Committee on Graduate Studies (COGS). If the application includes a Supervising Professor, Supervising Committee, and research project, the MSCI Admissions Committee will review for inclusion in the recommendation to the MSCI COGS.

The MSCI Admissions Committee will review each application individually and will consider: the applicant's undergraduate and graduate course work and degree(s), scores on the GRE and TOEFL (if applicable) tests, research experience, and all other required documentation submitted with the online application or sent directly to the MSCI Academic Coordinator. Research experience is not required but may be beneficial.

After sequential review by the MSCI Admissions Committee, the MSCI COGS, and the GSBS, applicants will be formally notified of the outcome by the Graduate Dean of the UT Health Science Center at San Antonio. The MSCI COGS recommends admission to the most highly qualified applicants regardless of ethnicity, gender, age, sexual orientation, nation of origin, or disability.

approved Supervising Professor. An Supervisory Committee, and research project are required for the successful completion of the MSCI Program; however, they are not a prerequisite in consideration for admission into the program unless entering the MSCI Program on a F-1 visa. For applicants who anticipate completion of the requirements for graduation within 2 years, it is highly recommended that the Supervising Professor, Supervising Committee, and research project, be identified and submitted for review at the time of initial application into the program.

If an applicant has completed all required MSCI courses as a non-degree seeking student in the GSBS, they must be eligible to enroll in the MSCI course, Mentored Research in Clinical Investigation (MEDI 6097), at the time of application to the program, *i.e.*, they must have identified a Supervising Professor, Supervising Committee, and research project.

After acceptance, students may complete the requirements for graduation while enrolled as either a full-time or part-time student.

Tuition and Fees

Tuition and Fees. Rates for in-state and outof-state student <u>tuition</u> and <u>fees</u> are established by the institution and subject to adjustment. A summary of current rates is provided in the Appendix.

Student Pathways in the MSCI Program

Regular Students. After acceptance as a candidate working towards the MSCI degree, students may undertake course requirements for graduation while enrolled as either a full-time or part-time student. Once a mentored research project is approved by the MSCI COGS (as described below, this is typically completed before initial enrollment for full-time students or established during the first year after admission

for part-time students), students may enroll in and receive up to three hours of research credit each semester.

Full-Time students. Full-time work is regarded as enrollment in at least nine (9) semester credit hours (SCH) during the Fall and Spring semesters or six (6) credit hours in the Summer semester. For students with an approved mentored research project, this is usually six hours of didactic seminars/lectures and three hours of research credit. Thus, to enroll as a full-time student upon admission, students must have an approved Supervising Professor, Supervising Committee, and research project at the time of application into the program. If the Supervising Professor, Supervising Committee, and research project are established and approved by the MSCI COGS at the time of admission, full-time students can expect to complete the course requirements for an MSCI within 2 years.

Part-time Students. Part-time students are enrolled for **less than** nine (9) credit hours per semester during the Fall or Spring or less than 6 credit hours per semester during the Summer. Earning the MSCI degree as a part-time student will usually require 3-4 years.

UT Health Science Center at San Antonio Faculty and Staff as Students in the MSCI Program. UT Health Science Center at San Antonio faculty and staff may apply for admission in the MSCI Program. However, faculty and staff may only enroll in coursework as a part-time student. The amount of course work that can be taken by faculty or staff in a given semester is subject to the 'quantity of work' rules outlined in the current UT Health Science Center at San Antonio Catalog and Handbook of Operating Procedures (HOP).

Foreign Nationals as Students in the MSCI Program. Consistent with the aims of the MSCI Program, the MSCI COGS firmly believes that enrollment in courses related to the conduct of clinical investigation is directly relevant to the research education of fellows and trainees at the UT Health Science Center at San Antonio. As a consequence, denying access to the MSCI courses to foreign nationals (persons at UT Health Science Center at San Antonio on a J-1 or H-1B visa) potentially puts them at a disadvantage in their research education and experiences. Additionally, the MSCI Program will directly benefit the J-1 and H-1B visa programs because the skills taught in the MSCI courses will enhance the quality of the candidates' work that they were hired to do under the auspices of these visas.

Accordingly, the MSCI COGS has agreed to the following enrollment principles for persons with J-1 or H-1B visa status.

- 1. They may be accepted as a candidate working towards the MSCI degree, but enrollment in classes must be incidental to their primary activities for which they came to the UT Health Science Center at San Antonio.
- 2. They may enroll in up to three credit hours of didactic course work per semester; enrollment in more semester hours requires prior approval from the Office of International Services. These three credits will be in formal lecture and seminar courses which are 'incident to' the purpose of the visa. Three credit hours is less than half of the semester credit hours considered to constitute full-time enrollment in the UT Health Science Center at San Antonio Graduate School of Biomedical Sciences (GSBS). Thus, these individuals will be part-time graduate students.
- 3. They may enroll in research credits under the supervision of their Supervising Professor. This credit is directly relevant to and obtained from the work these individuals are conducting in the United States. Enrollment for research credit is based upon the discussion and discretion of the MSCI Committee on Graduate Studies (MSCI COGS), Program Director, and the individual's Supervising Professor. The number of research credits allowed per semester will be determined on a case-bycase basis, based on the individual circumstances of the student.
- 4. At no time, will participation in the MSCI Program interfere with the timely completion of the duties and responsibilities

for which the visa status was granted to the individual for admission to the United States.

These principles assure that the Federal Rules and Regulations for the visa process are upheld while creating a pathway by which foreign nationals may participate in clinical research education at UT Health Science Center at San Antonio.

Foreign nationals who seek admission to the MSCI Program as full-time students may do so under an F-1 Student Visa.

For all foreign nationals with a J-1, H-1B, or F-1 visa who are enrolled in the MSCI Program, a letter of continued support from the Supervising Professor must be submitted bi-annually (prior to enrollment in the Fall and Spring semesters).

Non-Degree Seeking Students in the GSBS. Non-degree seeking students may enroll in MSCIsponsored courses and receive GSBS course credit without matriculation (admission) into the MSCI Program. Note: non-degree seeking students in the GSBS are *independent* of the MSCI Program. For those not already matriculated into other GSBS graduate programs, an on-line application must be submitted to the GSBS for approval by the Dean [this would also include students who are matriculated in other UT Health Science Center at San Antonio Schools (e.g., Medical School or Dental School) as well as faculty, staff, or others]. The appropriate MSCI Course Director must approve the enrollment of any non-degree seeking student in their course and sign course cards (provided by the GSBS Dean's office).

Course credit earned as a non-degree seeking student can be applied towards an MSCI degree following formal application and acceptance into the MSCI Program. An MSc Degree in Clinical Investigation **cannot** be obtained as a non-degree seeking student. Note that enrollment as a nondegree seeking student in the GSBS is limited to 4 semesters. Additional details about non-degree seeking students are available at:

UT Health Science Center at San Antonio GSBS website

Degree Requirements

Successful completion of the MSCI Program requires the satisfactory completion of required coursework, completion of an approved research project and the submission of a peer-reviewed publication related to the approved research project.

Research Project. A Supervising Professor, Supervising Committee, and written research proposal must be approved by the MSCI COGS (see details provided below).

Manuscript. Upon satisfactory completion of all required courses, and with the approval of the Supervising Professor and Supervising Committee, students must submit a manuscript to the MSCI COGS for review for their eligibility for candidacy for the MSCI degree. The manuscript must be accompanied by a completed copy of the *Manuscript Approval Form* and a letter from the Supervising Professor attesting to the student's participation in all the stages of research and development of the manuscript.

Coursework. Thirty semester credit hours (SCH) are required to obtain the MSCI degree. Students must satisfactorily complete all *required courses*. The student in consultation with the Supervising Professor and the Supervising Committee will select elective courses from an approved list of courses. Exceptions to participation in required courses must be approved by the MSCI COGS and will be evaluated on a case-by-case basis after submission of a written request from the student with co-signature of the Supervising Professor (if applicable).

Supervising Professor, Supervising Committee, and Research Project

A student must identify a Supervising Professor, establish a Supervising Committee, and select a research area of interest. Each of these must be approved by the MSCI COGS as outlined below.

Supervising Professor. The Supervising Professor will oversee all aspects of the student research project and must be a member of the MSCI Graduate Faculty. In the event that a student identifies a Supervising Professor who is not a member of the MSCI Graduate Faculty, the MSCI COGS will separately assess the individual qualifications of that for recommendation to the GSBS for appointment to the MSCI Graduate Faculty (see below). Requests for consideration of appointment to the MSCI Faculty considered Graduate may be concomitantly with the evaluation of an individual to serve as a student's Supervising Professor. No mentor may have more than 5 MSCI students at a given point in time; exception to this limit requires special consideration by the MSCI COGS.

The proposed Supervising Professor must submit a letter of commitment to the MSCI Program Director through the MSCI Academic Coordinator that includes:

- Brief overview of the planned research project (to be reviewed/approved by the Supervising Committee once established)
- Description of the student's role/activities in the research project
- Statement of commitment to the student's education and training throughout the interval of the student in the MSCI Program
- If the student is a foreign national on a J-1, H-1B, or F-1 visa, an agreement to provide a bi-annual statement regarding continued support for enrollment in the MSCI Program

Supervising Committee. The student, with the help of his/her Supervising Professor, will choose a Supervising Committee. The Supervising Committee shall consist of the Supervising Professor (chair) and at least two members of the Graduate Faculty of the MSCI Program (including one member of the MSCI COGS); an optional additional committee member may be added to provide specific expertise in the planned area of study. It is the responsibility of the Supervising Professor and Student to present the proposed composition of the Supervising Committee to the MSCI COGS for approval.

The Supervising Committee must be established by the beginning of the first semester of enrollment for full-time students (in order to register for MEDI 6097 – *Mentored Research in Clinical Investigation*), or within 90 days following the approval of a Supervising Professor for part-time students.

Research Project. The first duty of the Supervising Committee will be to assist the student in (1) planning his/her research project, and (2) approving the research proposal for review by the MSCI COGS. It is anticipated that the project/written proposal will be the students' work. If the proposed studies are taken from an existing grant/protocol of the Supervising Professor, a separate cover letter from the Supervising Professor must be included to explicitly describe the proposed role/activities of the student. The written proposal should not exceed *six* double-spaced typewritten pages and should include the following sections:

- 1. Hypothesis
- 2. Specific Aims
- 3. Significance (with background, references, and rationale for the proposed studies)
- 4. Experimental Design (including the number of planned subjects/observations and statistical analyses)
- 5. References (*not included in the 6 page limit*)

Once the written research proposal has been approved by the Supervising Committee, the proposal shall be forwarded to the MSCI COGS for review and acceptance. After MSCI COGS approval, the student will begin participating in mentored research activities under the direction of the Supervising Professor and register to receive research course credit (*MSCI 6097 – Mentored Research in Clinical Investigation*). A grade of "Unsatisfactory" (U) for 50% or more course credit hours (semester hours) in research shall be grounds for recommendation (to the Dean of the GSBS) for dismissal from the Program.

Change in Supervising Professor, Supervising Committee or Research Project. If it becomes necessary for a student to change his/her Supervising Professor, Supervising Committee or research project after approval by the MSCI COGS, the MSCI COGS must review any changes prior to implementation.

Changing a Supervising Professor. Any change in the designated Supervising Professor requires review and approval by the MSCI COGS. This request should be submitted in writing to the MSCI Program Director through the MSCI Academic Coordinator and should include:

- Cover memo that describes the basis for the request to change the Supervising Professor
- A letter of commitment from the proposed Supervising Professor (with details as described above for the initial Supervising Professor's letter of commitment)
- NIH Biosketch of the proposed Supervising Professor
- <u>Request to Amend MSCI Student Research</u> <u>Program</u> Form (see Appendix)

Changing a Supervising Committee. Any change in membership in an approved Supervising Committee requires review and approval by the MSCI COGS. This request should be submitted in writing to the MSCI Program Director through the MSCI Academic Coordinator and should include:

- Cover memo that describes the basis for the request to change the Supervising Committee membership
- <u>Request to Amend MSCI Student Research</u> <u>Program</u> Form (see Appendix)

Changing a Research Project. Significant changes in the planned research project (*e.g.*, addition or deletion of a Specific Aim or substantial modifications in experimental design or scope of research studies to be undertaken) must be reviewed and approved by the Supervising Professor and Supervising Committee prior to consideration by the MSCI COGS. The written request to change the research project must be submitted to the MSCI Program Director through the MSCI Academic Coordinator and should include:

• The revised research proposal (with details as described above for the initial research proposal)

- Cover memo that describes the basis for the request to change the research project
- <u>Request to Amend MSCI Student Research</u> <u>Program</u> Form (see Appendix)

Manuscript Requirement

A basic tenet of the MSCI Program is the expectation that MSCI students should make a significant contribution to the peer reviewed literature. Thus, upon satisfactory completion of all required courses, and with the approval of the Supervising Professor and Supervising Committee, each student is required to submit a manuscript to the MSCI COGS for consideration of their eligibility for candidacy for the MSCI degree.

- The manuscript must have already been submitted to a peer reviewed scientific journal

 it may have been submitted, *in press*, or published during the interval that the student was enrolled in the MSCI Program.
- Manuscripts unrelated to the approved research project, such as case reports or book chapters, are not acceptable for completion of the manuscript requirement of the MSCI degree.
- Students are not required to be the first author on the manuscript, but must be a primary author. It is expected that students will be (or will share the position of) the primary author and that the manuscript will address the research project that has been approved by the MSCI COGS. In the event that either of these is not the case, a written explanation must be provided by the Supervising Professor.
- The manuscript should be provided to the Supervising Committee for review and approval *at least* 2 weeks prior to submission to the MSCI COGS. When submitted to the Supervising Committee:
 - The manuscript must be accompanied by a letter from the Supervising Professor that details the extent of the student's participation in each and every stage of the research as well as their involvement/role

in the development and preparation of the manuscript.

- It is anticipated that the manuscript will be evaluated by the Supervising Committee prior to submission for publication.
- After approval by the Supervising Committee, the Manuscript Approval Form of the MSCI Student Supervising Committee (see Appendix) should be completed and signed/dated by all members of the Supervising Committee.
- The manuscript can be submitted to the MSCI COGS at any time, however, in cases with impending graduation deadlines, the approved manuscript should be provided to the MSCI COGS *at least one month prior* to the regularly-scheduled graduation date established by the Graduate School of Biomedical Sciences (GSBS). When the manuscript is submitted to the MSCI COGS, it should be accompanied by:
 - A copy of the letter from the Supervising Professor (described above)
 - A dated notice (letter or email) from the publisher that indicates manuscript submission/acceptance
 - The completed <u>Manuscript Approval</u> <u>Form</u> of the MSCI Student Supervising Committee (see Appendix)

In keeping with the responsible conduct of research, all manuscripts must comply with the specific requirements of the journal (e.g., responsibilities of the corresponding author). There will be no exception to this requirement.

The MSCI manuscript requirement is the same for all students enrolled in the MSCI Program.



Coursework & Grading

Thirty semester credit hours (SCH) are required to obtain the MSCI degree.

Required Courses. Degree-seeking students in MSCI Program must successfully complete the following didactic courses.

MEDI 5070	Responsible Conduct of Patient-
(2 SCH)	Oriented Clinical Research
MEDI 5071	Patient-Oriented Clinical
(2 SCH)	Research Methods -I
MEDI 5072	Patient-Oriented Clinical
(2 SCH)	Research Biostatistics - I
MEDI 5073 (2 SCH)	Integrating Molecular Biology with Patient-Oriented Clinical Research
MEDI 5074	Data Management, Quality
(2 SCH)	Control, and Regulatory Issues
MEDI 5075 (2 SCH)	Scientific Communication
MEDI 6060	Patient-Oriented Clinical
(2 SCH)	Research Methods -2
MEDI 6061	Patient-Oriented Clinical
(2 SCH)	Research Biostatistics - 2
MEDI 6065 (2 SCH)	Health Services Research

Exemptions to the requirement for completion of a required course will be considered by the MSCI COGS on a case-by-case basis. A written request for exemption must be submitted to the MSCI Program Director through the MSCI Academic Coordinator and should include a brief description of the reason(s) for the request. In the event that prior coursework conducted at another institution is the basis for the request, details regarding the content of the substitute course(s) must be provided. MSCI COGS approval of a request for exemption to a required course does not automatically result in approval of course credit hours towards the MSCI degree. Transfer of coursework for credit is described below.

Research Course. In a given semester, MSCI students with an approved research project may enroll to receive course credit (3 hours) for research, *i.e.*, after MSCI COGS approval of the Supervising Professor, Supervising Committee, and research project:

MEDI 6097	Mentored Research in Clinical
(3 SCH)	Investigation

Although it is possible to enroll for more than 3 hours of research credit in any given semester, approval of greater than 3 hours requires special consideration and approval by the MSCI Program Director and will be considered on a case-by-case basis. A written request for exemption must be submitted to the MSCI Program Director through the MSCI Academic Coordinator (in advance of registration) and should include a brief description of the basis of the request.

Elective Courses. Diverse elective courses are sponsored by the MSCI Program and are available to MSCI graduate students. These courses may be taken in any semester when offered and include:

MEDI 6064	Grantsmanship and Peer
(1 SCH)	Review
MEDI 6066	Instrument Development and
(1 SCH)	Validation
MEDI 6067	Genetics Primer for Patient
(1 SCH)	Oriented Research
MEDI 6068	Cross Cultural Adaptation of
(1 SCH)	Research Instruments
MEDI 5076 (1 SCH)	Introduction to Informatics

MEDI 5077	Translational Science
(1 SCH)	Practicum
MEDI 6100	Practicum in IACUC
(1 SCH)	Procedures
MEDI 6101 (1 SCH)	Topics in Translational Science
MEDI 6102 (1 SCH)	Practicum in IRB Procedures
MEDI 6103	Selected Topics in Advanced
(1 SCH)	Research Ethics
MEDI xxxx	Introduction to Translational
(1 SCH)	Science

A typical schedule for a full-time MSCI student is provided in the Appendix together with descriptions of MSCI Program-sponsored courses and their learning objectives.

Grade Requirement. Student performance in MSCI-sponsored Program courses is assessed on a satisfactory (S) / unsatisfactory (U) basis. Any student who receives less than a Satisfactory (S) assessment in any of the requisite MSCI core courses will be required to re-take the course and receive a passing grade during the next academic year. In the event of a second failure in the same course, the Student Advisory Subcommittee of the MSCI COGS will provide a recommendation as to whether or not the student is to be dismissed from the MSCI Program.

Transfer of Coursework for Credit. If a student has successfully completed graduate level coursework that is duplicative of required or elective MSCI courses, it is possible that transfer of course credit may be allowed. A written request for consideration of transfer of course credit in substitution for a given MSCI course must be submitted to the MSCI Program Director through the MSCI Academic Coordinator. This request should include a comprehensive description of the prior course detailing when and where completed,

course contact hours, and details of course content and objectives. The request should include an official transcript that indicates successful course completion and the grade issued. If the transfer of credit request is approved by the MSCI COGS, the program will prepare a request for transfer of course credit (on GSBS forms) and submit to the GSBS for consideration/approval by the Dean. In no case will the allowable semester credit hour(s) of transfer for a given course exceed that of the corresponding MSCI course. As per GSBS rules, no more than 6 semester credit hours may be transferred towards the completion of a Masters of Science degree.

Class Attendance and Makeup Policy

Attendance. The UT Health Science Center at San Antonio MSCI faculty believe that attendance at scheduled classes and examinations is crucial to meeting course and program objectives. Therefore, regular attendance in class is expected of each student. Attendance is defined as being present within 15 minutes after the scheduled beginning the class and until 15 minutes before the scheduled ending of the class.

Excused absences may be granted by the Instructor in cases such as formal presentations at scientific meetings, illness, or personal emergency. Excused absences are considered on an individual basis and require electronic communication with the Course Director to request an excused absence. The email request to the Course Director for consideration of an excused absence must provide details regarding the circumstances and specific dates. It is expected that students will provide advanced *notice* of absence for scheduled events.

Repeated unexcused absences make it impossible to achieve course objectives. Thus, if a student has excessive unexcused absences in a given course, they will automatically receive a grade of *unsatisfactory* unless *makeup* has been approved by the Course Director (see below). Assuming that most MSCI courses are 2 hour class sessions, allowable unexcused absences will be determined by the credit hours of the course as follows:

Course Credit Hours	Allowable Unexcused Absences
3	3
2	2
1	1

Absence Makeup. Makeup of absences (both excused and unexcused) is allowed at the discretion of the Course Director.

Other MSCI Program Requirements

All wireless laptops must be authenticated before accessing the UT Health Science Center at San Antonio computer network. To accomplish this authentication, the laptop and an UT Health Science Center at San Antonio ID card must be taken to UT Health Science Center at San Antonio Telecommunications & Networking (Room 421L) *prior* to the start of classes; this authentication process usually requires approximately 5 minutes.

Evaluation of Student Progress. As described in detail below, MSCI students with an approved research project shall prepare a semi-annual written report of progress for consideration by their Supervising Committee. The completed *Semi-Annual MSCI Student Evaluation Form* and the *Student Progress Form* of the MSCI Supervising Committee must then be submitted to the MSCI Program Director through the MSCI Academic Coordinator (see below).



Laptop Computer Requirement. The MSCI Program requires that regular students have an Intel-based laptop computer with the capacity to connect to the internet via a wireless connection. Some MSCI classes will involve the use of laptop computers that are operational in a wireless mode. Software required on each laptop includes:

- Microsoft Office Suite (can be purchased at the UT Health Science Center at San Antonio bookstore with a student ID)
- Stata/IC (latest version) <u>http://www.stata.com/order/new/edu/gr</u> <u>adplans/gp-campus.html</u>

Laptops with an Apple Mac-based operating system must be able to also perform as a PC-based operating system.

Semi-Annual Student Evaluation

Students with an approved research project will be evaluated by the Supervising Professor and Supervising Committee *at least once every six months throughout the remainder of their enrollment in the MSCI Program.* Following MSCI COGS approval of the research project, semi-annual progress reports must be submitted to the MSCI COGS by *August 31 and February 28* of each year irrespective of the date of MSCI COGS approval of the research project. Once a student has completed all requirements for completion of the MSCI Program, no further semi-annual evaluations will be required.

Requests for extension of the deadline for submission of all documents associated with the semi-annual evaluation (see below) will be considered on a case-by-case basis. A written

request for extension should be directed to the MSCI Program Director through the MSCI Academic Coordinator and should describe the reason for the request; this letter must include the signature of the Supervising Professor. Requests must be received by the final Friday of the month prior to the due date of the evaluation. Failure to submit completed, signed forms included in this required semi-annual evaluation or to provide a letter requesting an extension of the deadline will result in a grade of unsatisfactory for the research course (MEDI Mentored Research 6097. in Clinical Investigation) in the corresponding semester (Fall semester for the August 31 deadline and Spring semester for the February 28 deadline).

To accomplish this evaluation, the student shall submit to the Supervising Committee a written report of progress on their research work, including statements of objectives of the research, methods used, major results obtained, conclusions drawn, pre- or reprints of papers submitted for publication, and proposed direction of future work. This will involve completion of the MSCI Semi-Annual Student Evaluation Form (by the student and Supervising Professor) and a formal meeting of the student's Supervising Committee. The Supervising Professor shall serve as the Chairman and is expected to establish the time and place of the meeting. The student shall be present during this formal meeting of the Supervising Committee and is expected to provide a brief overview of his/her research and training activities, any problems encountered since the meeting with Supervising previous the Committee, as well as plans for the future towards completion of the requirements in fulfillment of the MSCI Program. If requested, the student may be asked to leave the meeting during Supervising Committee's deliberations. The Supervising Committee will evaluate the research progress made by the student and, if satisfactory, endorse both the progress and the direction of future work to be undertaken. This semi-annual evaluation will include consideration of student participation in and satisfactory completion of required MSCI course work, research, seminars and other MSCI Program activities.

If progress is unsatisfactory, the Supervising Committee shall discuss the reasons for this decision with the student. Then, the Supervising Professor and student shall develop a plan for remediation. In this case, the student shall present an updated <u>MSCI Semi-Annual Student Evaluation</u> Form to the Supervising Committee within three months.

The Supervising Professor will follow up each meeting with a memorandum to every member of the Supervising Committee specifying the Supervising Committee's decisions regarding the outcome of student evaluation including research progress and future work. A copy of this memorandum should be provided to the MSCI Program Director through the MSCI Academic Coordinator together with a copy of the MSCI Semi-Annual MSCI Student Evaluation Form and the Student Progress Report Form of the Supervising Committee (see Appendix) for processing and further review by the MSCI Student Advisory Subcommittee prior to presentation to the MSCI COGS.

Failure of a student to show satisfactory progress toward his/her degree goal may be grounds for dismissal from the Program. The MSCI COGS, in consultation with the Supervising Professor, will make the final decision regarding a recommendation for student dismissal (to be submitted to the Dean of the GSBS). The Dean of the GSBS will be notified of any student who receives unsatisfactory evaluations in two consecutive periods.

The Supervising Professor, with the advice and consent of the Supervising Committee, shall decide when the student has completed a body of research work that meets the degree requirements for MSCI Program. Each graduate of the MSCI Program should make a significant contribution to the peer-reviewed biomedical or clinical literature (see *Manuscript Requirement*).

Ethics/Professionalism Policy

The MSCI Program expects all students to exhibit the highest standards of conduct, honesty, and professionalism. Academic misconduct includes activities that undermine the academic integrity of the institution. The University may discipline a student for academic misconduct as outlined in the UT Health Science Center at San Antonio Catalog and Handbook of Operating Procedures. Academic misconduct may involve human, hard-copy, or electronic resources. Policies of academic misconduct apply to all course-, department-, school-, and universityrelated activities including conferences and offcampus performances as well as research work (including lab experiments, data collection and analyses). All cases of academic misconduct must be reported to the Dean of the Graduate School of Biomedical Sciences (GSBS) and the seriousness of the violation may be taken into account in assessing a penalty. Academic misconduct includes, but is not limited to, the following:

Cheating. Any attempt to use or provide unauthorized assistance, materials, information, or access in any form and in any academic exercise or environment is considered cheating and is expressly forbidden.

Fabrication. A student must not falsify or invent any information or data including, but not limited to, records or reports, laboratory results, data analyses, and citation to the sources of information.

Plagiarism. Plagiarism is defined as presenting someone else's work as one's own. Ideas or materials taken from another source for either written or oral use must be fully acknowledged. The adoption or reproduction of ideas, opinions, theories, formulas, graphics, or research results of another person without acknowledgment is expressly forbidden. Credit must be given to the originality of others whenever:

- Quoting the works of another
- Using another person's ideas, opinions, or theories

- Paraphrasing the words, ideas, opinions, results, or theories of others
- Borrowing facts, statistics, or illustrative material
- Offering materials assembled or collected by others

Facilitating Academic Dishonesty. A student must not intentionally or knowingly help another student commit an act of academic misconduct, nor allow another student to use his/her work or resources to commit an act of misconduct.

MSCI (Programmatic) Graduate Faculty

The MSCI COGS assesses the qualifications of each individual prior to recommendation to the Dean of the GSBS for their appointment to the MSCI Graduate Faculty. The following must be submitted *via* e-mail to the MSCI Academic Coordinator for MSCI COGS assessment:

- NIH Biosketch (PDF)
- <u>MSCI Graduate Faculty Trainee Table</u> (Form)

In consideration of individuals for membership in the MSCI Graduate Faculty, emphasis will be placed upon the following:

- Experience and accomplishments in the provision of mentored research training
- Availability of research funding to support a student's mentored research project
- Research productivity (publications)
- Teaching excellence
- Other scholarly activities

Consistent with the by-laws of the GSBS, all MSCI Graduate Faculty will be automatically reviewed at least once every three (3) years. Requests for appointment to the MSCI Graduate Faculty may be considered concomitantly with the evaluation of an individual to serve as a student's Supervising Professor.

A list of current MSCI Graduate Faculty is included in the Appendix

Completion of the MSCI Program

Recommendation for Granting the MSCI Degree. Upon satisfactory completion of all degree requirements, the MSCI COGS must review and approve the recommendation for graduation; the MSCI COGS Chair will then submit a recommendation form to the *Graduate Faculty Council* (GFC) of the Graduate School of Biomedical Sciences (GSBS) for further consideration and approval.

Time-to-Masters Degree. It is expected that that the MSCI Program can be completed in 2 years of full-time work. Part-time students may require 3 to 4 years to complete the degree requirements. If an MSCI student who enrolled full-time has not graduated in 3 years (or a parttime student has not graduated in 4 years), the MSCI COGS Chair will form a special committee independent of the Student's Supervisory Committee to review progress with the student and his/her advisor. The special committee's responsibility will be to either recommend a course of action to expedite graduation or recommend termination of the enrollment of the student in the program.



2005 MSCI Graduates, Hernan Rincon-Choles (left) and Javier Hernandez (right), with MSCI Program Director, Michael Lichtenstein (center)



2009 MSCI Graduates, Shivani Maffi (2nd from left) and Ismail Sahar (right), with Robert Reddick, the Interim Dean of the Graduate School of Biomedical Sciences (3rd from left) and the MSCI Program Associate Director, Linda McManus (left)

Helpful Online Connections

MSCI Program	<u>http://iims.uthscsa.edu/ed_msci_overview.ht</u> <u>ml</u>
MSCI Forms	http://iims.uthscsa.edu/ed_msci_forms.html
<u>Graduate School of Biomedical Sciences (GSBS)</u>	http://gradschool.toolbox.net/
GSBS Application for Admission	http://apply.embark.com/grad/UTHSCSA/
<u>GSBS Deadlines for Admission</u>	http://studentservices.uthscsa.edu/pdf/Grad ViewbkWeb08.pdf
Office of Student Services (Registrar)	http://studentservices.uthscsa.edu
Class Times and Locations	http://studentservices.uthscsa.edu/GI_sched ules.aspx
<u>Student Services International Student Information</u> and Approved Foreign Credentialing Agencies	http://studentservices.uthscsa.edu/CS_intern ational.aspx
Office of International Services	http://www.uthscsa.edu/ois
<u>UT Health Science Center Catalog</u>	http://studentservices.uthscsa.edu/publicatio ns/Catalog.html
<u>UT Health Science Center Handbook of Operating</u> <u>Procedures (HOP)</u>	http://www.uthscsa.edu/hop2000/
Institute for the Integration of Medicine and Science	http://iims.uthscsa.edu/index.html

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2010-2011 Committee on Graduate Studies (MSCI COGS)

Master of Science in Clinical Investigation (MSCI)

Michael Lichtenstein, MD, MSc MSCI COGS Chairman

Carrie Jo Braden, RN, PhD Nursing

David M. Bush, MD, PhD Brooke Army Medical Center Clinical Investigation

David P. Capelli, DMD, PhD, MPH Community Dentistry

Barbara A. Christy, PhD Molecular Medicine

Robert A. Clark, MD Medicine

John E. Cornell, PhD Medicine/Geriatrics

Betty Dunn, MS Clinical Lab Sciences

Sharon P. Fowler, MPH Medicine/Clinical Epidemiology Goutam Ghosh-Choudhury, PhD Medicine/Nephrology

Helen P. Hazuda, PhD Medicine/Clinical Epidemiology

Angela Khan Institutional Review Board

Donna M. Lehman, PhD Medicine/Clinical Epidemiology

Michael J. Lichtenstein, MD Medicine/Geriatrics/GCRC

Philip T. LoVerde, PhD Biochemistry/Pathology

Bettie Sue Masters, PhD Biochemistry

Linda M. McManus, PhD Pathology **Douglas L. Murphy, PhD** School of Health Professions

Polly H. Noel, PhD Medicine/General Medicine

Michael L. Parchman, MD Family and Community Medicine

Brad H. Pollock, PhD Biostatistics and Epidemiology

Steven Schenker, MD Medicine/Gastroenterology

John D. Schoolfield, MS Academic Information Services

Z. Dave Sharp, PhD Molecular Medicine

Ximena Urrutia-Rojas, RN, DPH, MPH UT School of Public Health

2010-2011 MSCI Graduate Faculty

Master of Science in Clinical Investigation (MSCI)

Hanna E. Abboud, MD Medicine/Nephrology

Muhammad A. Abdul-Ghani, PhD Medicine/Diabetes

Seema Ahuja, MD Medicine/Nephrology

Sunil K. Ahuja, MD Medicine/Infectious Disease

Bennett T. Amaechi, BDS, PhD Community Dentistry

Antonio R. Anzueto, MD Medicine/Pulmonary Disease

Nedal Arar, PhD Medicine/Nephrology

Santanu Bose, PhD Microbiology

Charles L. Bowden, MD Psychiatry

Carrie Jo Braden, RN, PhD Nursing

Robin Brey, MD Medicine/Neurology David M. Bush, MD, PhD Brooke Army Medical Center Clinical Investigation

David P. Capelli, DMD, PhD, MPH Comprehensive Dentistry

Eugenio Cersosimo, MD Medicine/Diabetes

Bandana Chatterjee, PhD Molecular Medicine

Barbara A. Christy, PhD Molecular Medicine

Robert A. Clark, MD Medicine

David L. Cochran, DDS, PhD Periodontics

John E. Cornell, PhD Epidemiology & Biostatistics

Kenneth Cusi, MD Medicine/Diabetes

Ralph A. DeFronzo, MD Medicine/Diabetes

Donald J. Dudley, MD Obstetrics and Gynecology Betty Dunn, MS Clinical Lab Sciences

Agustin Escalante, MD Medicine/Clinical Immunology

Robert L. Ferrer, MD Family and Community Medicine

Sharon P. Fowler, MPH Medicine/Clinical Epidemiology

SJ Gao, PhD Pediatrics

Goutam Ghosh-Choudhury, PhD Medicine/Nephrology

Alice K. Gong, MD Pediatrics

Daniel E. Hale, MD Pediatrics

Kenneth M. Hargreaves, DDS, PhD Endodontics

Helen P. Hazuda, PhD Medicine/Clinical Epidemiology

Michael A. Henry, DDS, PhD Endodontics Alan E. Holden, PhD Obstetrics & Gynecology

Peter Hornsby, PhD Physiology

Fruzsina K. Johnson, PhD Surgery/Trauma Research

Robert A. Johnson, PhD Surgery/Trauma Research

Scott B. Johnson, MD Surgery

Balakuntalam S. Kasinath, MD Medicine/ Nephrology

Dean L. Kellogg, Jr, MD, PhD Medicine/Geriatrics

Nancy D. Kellogg, MD Pediatrics

Angela Khan Institutional Review Board

George B. Kudolo, PhD Clinical Laboratory Sciences

Valerie A. Lawrence, MD Medicine/General Medicine

Robin J. Leach, PhD Cellular and Structural Biology

Donna M. Lehman, PhD Medicine/Clinical Epidemiology Senlin Li, MD Medicine/Infectious Disease

Michael J. Lichtenstein, MD Medicine/Geriatrics

Philip T. LoVerde, PhD Biochemistry/Pathology

Bettie Sue Masters, PhD Biochemistry

Donald C. McCurnin, MD Pediatrics

Linda M. McManus, PhD Pathology

Joel E. Michalek, PhD Epidemiology & Biostatistics

Claudia S. Miller, MD Family & Community Medicine

Michael J. Morris, MD Pulmonary/Critical Care Medicine Brooke Army Medical Center

Eric M. Mortensen, MD Medicine/General Medicine

Douglas L. Murphy, PhD School of Health Professions

Shamimunisa B. Mustafa, PhD Pediatrics

Polly H. Noel, PhD Medicine/General Medicine Barry K. Norling, PhD Comprehensive Dentistry

Thomas Oates, DDS, PhD Periodontics

Raymond F. Palmer, PhD Family & Community Medicine

Michael L. Parchman, MD Family and Community Medicine

Jay I. Peters, MD Medicine/Pulmonary

Brad H. Pollock, PhD Epidemiology & Biostatistics

Thomas Prihoda, PhD Pathology

Mary Jo Pugh, MD Epidemiology & Biostatistics

Rajam S. Ramamurthy, MD Pediatrics

Todd Rasmussen, MD Lackland AFB Vascular Surgery

Spencer W. Redding, DDS Comprehensive Dentistry

Arlan Richardson, PhD Cellular & Structural Biology

John D. Rugh, PhD Developmental Dentistry **Steven Schenker, MD** Medicine/Gastroenterology

John D. Schoolfield, MS Academic Information Services

Martin G. Schwacha, PhD Surgery/

Wayne H. Schwesinger, MD Surgery

Steven R. Seidner, MD Pediatrics

Z. Dave Sharp, PhD Molecular Medicine **Paula K. Shireman, MD** Surgery/Vascular Surgery

Linda A. Smith, PhD Clinical Laboratory Sciences

Ronald M. Stewart, MD Surgery

Rajeshwar R. Tekmal, PhD Obstetrics and Gynecology

Ian M. Thompson, Jr., MD Urology **Devjit Tripathy, MD** Medicine/Diabetes

Ximena Urrutia-Rojas, RN, DPH, MPH UT School of Public Health

Ratna K. Vadlamudi, PhD Obstetrics & Gynecology

Charles Wade, MD Brooke Army Medical Center Institute for Surgical Research

Steven E. Wolf, MD Surgery/Burn & Trauma Surgery

Typical schedule for a full-time MSCI Student

Year 1 – Fall Semester

MEDI 5070 (2 hours) – Responsible Conduct of Patient Oriented Clinical Research MEDI 5071 (2 hours) – Patient Oriented Clinical Research Methods -1 MEDI 5072 (2 hours) – Patient Oriented Clinical Research Biostatistics -1 MEDI 6097 (3 hours) – Mentored Research in Clinical Investigation

Year 1 – Spring Semester

MEDI 5074 (2 hours) – Data Management, Quality Control, and Regulatory Issues MEDI 6060 (2 hours) – Patient Oriented Clinical Research Methods -2 MEDI 6061 (2 hours) – Patient Oriented Clinical Research Biostatistics -2 MEDI 6097 (3 hours) – Mentored Research in Clinical Investigation

Year 1 Summer Semester

MEDI 5073 (2 hours) – Integrating Molecular Biology with Patient Oriented Clinical Research *MEDI 6097 (3 hours) – Mentored Research in Clinical Investigation*

Year 2 – Fall Semester

MEDI 5075 (2 hours) – Scientific Communications MEDI 6065 (2 hours) – Health Services Research MEDI 6097 (3 hours) – Mentored Research in Clinical Investigation

Year 2 – Spring Semester* / graduation in May

MEDI 6097 (3 hours) – Mentored Research in Clinical Investigation

*No formal classes should be required during this semester. The research project should be completed and a manuscript prepared and submitted.

Thirty (30) credit hours are required to obtain the MSCI degree. Enrollment in *MEDI 6097 (Mentored Research in Clinical Investigation)* may occur in any semester after the Supervising Professor (research mentor) and project have been approved by the MSCI COGS. Students **must** be enrolled in the Graduate School in the semester of their graduation.

MSCI Elective Courses (may be taken in any semester when offered)

MEDI xxxx (1 hour) – Introduction to Translational Science
MEDI 5076 (1 hour) – Introduction to Informatics
MEDI 5077 (1 hour) – Practicum in Translational Science
MEDI 6100 (1 hour) – Practicum in IACUC Procedures
MEDI 6101 (1 hour) – Topics in Translational Science
MEDI 6102 (1 hour) – Practicum in IRB Procedures
MEDI 6103 (1 hour) – Selected Topics in Advanced Research Ethics
MEDI 6064 (1 hour) – Grantsmanship and Peer Review
MEDI 6066 (1 hour) – Instrument Development and Validation
MEDI 6067 (1 hour) – Genetics and Genetic Epidemiology
MEDI 6068 (1 hour) - Cross Cultural Adaptation of Research Instruments

Master's of Science Degree in Clinical Investigation (MSCI)

Typical timeline and sequence of MSCI courses for a full-time student

	Year 1 Year 2		2			
Semester	Fall	Spring	Summer	Fall	Spring	Summer
Required Courses						
Responsible Conduct of Patient Oriented Clinical Research (<i>MEDI 5070</i>)	2 hrs					
Patient Oriented Clinical Research Methods (MEDI 5071 & MEDI 6060)	2 hrs	2 hrs				
Patient Oriented Clinical Research Biostatistics (MEDI 5072 & MEDI 6061)	2 hrs	2 hrs				
Data Management, Quality Control, and Regulatory Issues (<i>MEDI 5074</i>)		2 hrs				
Integration of Molecular Biology with Clinical Research (MEDI 5073)			2 hrs			
Scientific Communication (MEDI 5075)				2 hrs		
Health Services Research (MEDI 6065)				2 hrs		
Mentored Research in Clinical Investigation (MEDI 6097)	3 hrs	3 hrs	**	3 hrs	3 hrs	**
TOTAL Credit Hours/Semester (30 hours required towards completion of MSCI)	9 hrs	9 hrs	2 hrs	7 hrs	3 hrs	
Elective Courses						
Grantsmanship and Peer Review (MEDI 6064)						
Instrument Development and Validation						
Genetics and Genetic Epidemiology						
Cross Cultural Adaptation of Research Instruments						
Introduction to Informatics						
Introduction to Translational Science (MEDI xxxx)						
Topics in Translational Science(MEDI 6101)						
Practicum in Translational Science (MEDI 5077)						
Practicum in IACUC Procedures (MEDI 6100)						
Practicum in IRB Procedures (MEDI 6102)						
Selected Topics in Advanced Research Ethics (MEDI 6103)						

** Students may take research credit during the summer session. (Full time summer enrollment is 6 semester credit hours)

MSCI Program Tuition and Fee Breakdown As of 01/07/2009 – Subject to Change

This is only an estimate – Tuition and Fees are subject to change without notice

Breakdown of Cost	Cost
Tuition - Texas Resident (per semester credit hour)	50.00
Designated Differential Tuition (per semester credit hour)	16.00
Tuition - Non-Texas Resident (per semester credit hour)	331.00
Designated Differential Tuition (per semester credit hour)	59.00
Fitness Center Fee	180.00
Student Service Fee (per semester credit hour)	7.50
Medical Service Fee	55.00
Library Fee (Fall & Spring ONLY)	100.00
Designated Tuition (per semester credit hour)	46.00
Diploma Fee (Semester Graduating)	60.00
Total semester credit hours (sch) to complete program is 30 sch	
Texas Resident	
Tuition (per sch):	1,500.00
Designated Dif Tuition (per sch):	480.00
*Fitness Center Fee (Full-time = 6 semesters):	1,080.00
Student Service Fee (per sch):	225.00
*Medical Service Fee (Full-time = 6 semesters):	330.00
*Library Fee (Full-time = 4 semesters):	400.00
Designated Tuition (per sch):	1,380.00
Diploma Fee (One-time FeeGrad Semester):	60.00
Total:	5,455.00
Non-Texas Resident	
Tuition (per sch):	9,930.00
Designated Dif Tuition (per sch):	1,770.00
*Fitness Center Fee (Full-time = <u>6 semesters</u>):	1,080.00
Student Service Fee (per sch):	225.00
*Medical Service Fee (Full-time = <u>6 semesters</u>):	330.00
*Library Fee (Full-time = <u>4 semesters)</u> :	400.00
Designated Tuition (per sch):	1,380.00
Diploma Fee (One-time FeeGrad Semester):	60.00
Total:	15,175.00

* Increasing the number of semesters needed to complete program will also increase the total cost.

Additional Costs Not Included: Purchase of laptop, software, books, and supplies

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI) Program CHECKLIST OF REQUIRED DOCUMENTATION FOR APPLICATION

	CHECKLIST OF REQUIRED DOCUMENTATION FOR APPLICATION
(Se	ee MSCI Handbook at <u>http://iims.uthscsa.edu/ed_msci_handbook.html</u> for full program requirements)
	Submit an on-line application to The UTHSCSA Graduate School: http://apply.embark.com/grad/UTHSCSA/
	Official transcripts of ALL colleges/universities attended sent from the institution (in a sealed envelope) to The UTHSCSA
	Registrar's Office as directed in the on-line application. Official translation of foreign transcripts including GPA of ALL foreign colleges/universities from credentialing
	agencies should be sent from the credentialing agency (in a sealed envelope) to The UTHSCSA Registrar's Office as directed in
	the on-line application. The translation must be from a credentialing agency approved by the UTHSCSA Registrar's Office. Three Letters of Recommendation (LOR) should attest to the applicant's readiness for graduate level studies in clinical
	investigation and be addressed to Dr. Michael Lichtenstein, MSCI Program Director. (Note: LOR's should be uploaded to
	your on-line application by the references you named in your on-line application.)
	For applicants from outside The UTHSCSA: LOR1 – Reference:
	LOR2 – Reference:
	LOR3 – Reference:
	For applicants from within The UTHSCSA participating as a resident or fellow in an approved
	residency or fellowship training program: LOR1 Department (Includes statement indicating the availability and approval of release time for the
	LOR1 Department (Includes statement indicating the availability and approval of release time for the completion of MSCI educational and research activities.)
	LOR2 – Reference:
	LOR3 – Reference:
	For applicants from within The UTHSCSA not participating in a residency or fellowship program: LOR1 – Authorized (Includes statement indicating the availability and approval of release time for the
	Supervisor completion of MSCI educational and research activities.)
	LOR2 – Reference:
_	LOR3 – Reference:
	General Record Examination (GRE) scores (exam taken within the past five years) sent directly to The UTHSCSA from the Educational Testing Service (ETS). UTHSCSA code: 6908 (<i>Note: The GRE is not required for applicants who have</i>
	completed a graduate degree in a health related discipline, i.e., a MSN, MD, DDS, or PhD.)
	Test of English as a Foreign Language (TOEFL) scores (test taken within the past two years) sent directly to
	The UTHSCSA from the ETS. UTHSCSA code: 6908 (<i>Note: The TOEFL is required for all non-US citizens whose first language is not English.</i>)
Ina	ddition to the above, the documents listed below are required and should be sent to:
<u></u>	Lora Tumlinson
	Academic Coordinator, MSCI Program
	UTHSCSA – IIMS/C-TREO – MC 7757 7703 Eloved Curl Drive
	7703 Floyd Curl Drive San Antonio, Texas 78229-3900
	Curriculum vitae (CV) of applicant.
	Statement of Purpose (Includes a brief description of the applicant's background, long term career goals, and
_	an indication of the basis for application into the MSCI Program.)
	Authorization for Security Background and Sanction Check form (Required before a recommendation for student admission can be forwarded to the Graduate School of Biomedical Sciences (GSBS) Dean's Office.)
	Copy of U.S. Medical License/Certificate
	*Supervising Professor's (primary research mentor) Letter of Commitment (Includes a brief description of
	the applicant's research project, the role of the applicant in the planned study, and a statement of commitment to
	the applicant's career development. If the applicant is on a J-1 Visa this letter should include a statement indicating that enrollment in MSCI classes is incidental to their primary activities for which they came to The
	UTHSCSA. (Note: If an applicant with a J-1 Visa is accepted, the Mentor will be required to submit a Letter of
_	Commitment at the beginning of each Fall and Spring semester.)
	*Supervising Professor's CV (Formatted as a four page NIH Biosketch) (Note: If your Supervising Professor is not a member of the MSCI Graduate Faculty please contact Lora Tumlinson at <u>tumlinson@uthscsa.edu</u> .)
	*Applicant's Supervising Committee
	Chair (Supervising Professor)
	MSCI Graduate Faculty member (at least one)
	MSCI COGS member

in the six page limit). *Required of applicants who seek enrollment as a full-time student.

CHECKLIST FOR RESEARCH PACKET

See MSCI Handbook for detailed program requirements.

Submission Deadlines:

	Academic Coordinator for MSCI COGS Monthly Meeting: June 1 st (Applicants requesting or transferring a F-1 Visa) Last Friday of July (Fall Semester Enrollment in MEDI 6097-Mentored Research) 3 rd Friday of November (Spring Semester Enrollment in MEDI 6097-Mentored Research) Last Friday of April (Summer Semester Enrollment in MEDI 6097-Mentored Research)
Re	quired Documentation:
	Please arrange in the order below before delivering to the MSCI Academic Coordinator.
	Supervising Committee List & Signature Approval of Research Project Form (Original) All information, complete names, dates, and signatures are provided on the form.
	Supervising Professor's Letter of Support (Original) Letter includes: Brief overview of the planned research project including the students role/involvement in the research project. Statement of commitment to the student's education and training throughout the interval of the student in the MSCI Program If the student is a foreign national (F-1 or J-1 visa), an agreement to provide a biannual statement regarding continued support for enrollment in the MSCI Program. Supervising Professor's Signature
	Research Plan Double-spaced, typewritten plan (6 page limit) includes: Hypothesis Specific Aims Significance (with background, references, and rationale for the proposed studies) Experimental Design (including the number of planned subjects/observations and statistical analyses) References (not included in the 6 page limit)

Supervising Professor's NIH Biosketch

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI) Program

CHECKLIST FOR MANUSCRIPT PACKET

See MSCI Handbook for detailed program requirements.

Submission Deadlines:

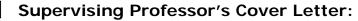
Super	vising Committee: <u>Two (2) weeks prior to submission to the MSCI COGS</u>
	1 st Week of October (Fall Semester Graduation) 1 st Week of March (Spring Semester Graduation)
	1 st Week of June (Summer Semester Graduation)
Acade	mic Coordinator for MSCI COGS Monthly Meeting: One (1) month prior to end of
	Last Friday of October (COGS November MeetingFall Semester Graduation)
	Last Friday of March (COGS April MeetingSpring Semester Graduation)
	Last Friday of June (COGS July MeetingSummer Semester Graduation)

Required Documentation:

Please arrange in the order below before delivering to the MSCI Academic Coordinator.

Manuscript Approval Form:

All information, complete names, dates, and signatures are provided on the form. Original Manuscript Approval Form



Letter includes the "details of the extent of the student's participation in each and every stage of the research as well as their involvement/role in the development and preparation of the manuscript."

Original Letter with Supervising Professor's Signature

Journal Dated Submission Notice:

All Confidential information has been blacked out. (i.e. Usernames, Passwords)

Copy of Original Letter or E-mail Please delete or black out any Usernames or Passwords provided to you by the journal allowing you access to their website.



Student Program Status Checklist

Student Program Status che	eckiist	
The information contained below is subject to change at the Program's and	/or Instructor's discretion with	out notice.
Course Catalog Number & Title	Semester	
REQUIRED – 2.0 sch (unless otherwise noted)	Course Schedule	Pre-Req
<u>YEAR 1:</u>		
Research Project Approved by MSCI COGS (Research Project Includes: Supervising Professor's Letter of Support & Bl & Approval Form, & Research Plan)	iosketch, Supervising Committ	ee List
MEDI 5070: Resp. Conduct of Patient Oriented Clinical Research	Fall Semester	
	Mondays, 3-5 p.m.	
MEDI 5071: Patient Oriented Clinical Research Methods – I	Fall Semester	
	Tuesdays, 3-5 p.m.	
MEDI 5072: Patient Oriented Clinical Research Biostatistics – I	Fall Semester	
	Thursdays, 3-5 p.m.	
MEDI 6097: Research (3.0 sch)	Fall Semester	*Approved
	MSCI Mentored Research	Research
MEDI 5074: Data Mgmt, Quality Control & Regulatory Issues	Spring Semester	
_	Tuesdays, 3-5 p.m.	
MEDI 6060: Patient Oriented Clinical Research Methods – II	Spring Semester	MEDI 5071
	Mondays, 3-5 p.m.	
MEDI 6061: Patient Oriented Clinical Research Biostatistics – II	Spring Semester	MEDI 5072
	Thursdays, 3-5 p.m.	**
MEDI 6097: Research (3.0 sch)	Spring Semester	*Approved
	MSCI Mentored Research	Research
MEDI 5073: Integrating Molecular Biology w/ Patient Oriented	Summer Semester	
Clinical Research	Mondays, Tuesdays, & Thursdays, 3-5 p.m.	
MEDI 6097: Research (3.0 sch)	Summer Semester	*Approved
	MSCI Mentored Research	Research
YEAR 2:		
MEDI 5075: Scientific Communication	Fall Semester	
	Wednesdays, 3-5 p.m.	
MEDI 6065: Health Services Research	Fall Semester	MEDI 5071
	Tuesdays, 3-5 p.m.	MEDI 6060
MEDI 6097: Research (3.0 sch)	Fall Semester	*Approved
	MSCI Mentored Research	Research
MEDI 6097: Research (3.0 sch)	Spring Semester	*Approved
	MSCI Mentored Research	Research
Manuscript Packet Approved by MSCI COGS		
(Packet Includes: Supervising Professor's Cover Letter, Journal's Dated No	otification of Submittal, & Man	uscript)
* 30 sch are required for MSCI Program Graduation. (Breakdown: 18 sch of	f required courses & 12 sch of i	research) *
Course Catalog Number & Title	Semester	
ELECTIVES – 1.0 sch (unless otherwise noted)	(Course Schedule)	Pre-Req

ELECTIVES – 1.0 sch (unless otherwise noted)	<u>(Course Schedule)</u>	Pre-Req
MEDI 6064: Grantsmanship & Peer Review	Spring Semester (TBA)	
MEDI 6066: Instrument Development & Validation	Spring Semester (TBA)	
MEDI 6067: Genetics & Genetic Epidemiology	Spring Semester (TBA)	
MEDI 6068: Cross-Cultural Adaptation of Research Instruments	s Spring Semester (TBA)	

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI) Program

Supervising Committee List and Signature Approval of Research Project

Applicant/Student Name:	Date:
Research Project Title:	
Signatures below affirm that the applicant/student approved.	's Research Planhas been reviewed, and
Supervising Committee:	
Chair (Supervising Professor)	
Signature:	
Printed or Typed Name:	
Department/Division:	
UTHSCSA E-mail Address:	
MSCI COGS Member	
Signature:	
Printed or Typed Name:	
Department/Division:	
UTHSCSA E-mail Address:	
MSCI Graduate Faculty Member	
Signature:	
Printed or Typed Name:	
Department/Division:	
UTHSCSA E-mail Address:	
(Optional) Expertise Specific UTHSCSA Faculty Member	
Signature:	
Printed or Typed Name:	
Department/Division:	
UTHSCSA E-mail Address:	

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI Program)

SEMI-ANNUAL STUDENT EVALUATION

Evaluation Process Instructions

Semi-annual Evaluation Process:

	Student completes information request on page 1, Sections I-III, and the Student Progress Report form.
	Student forwards evaluation (electronic copy) to Supervising Professor.
	Supervising Professor reviews Sections I-III completed by the Student. (If not in agreement the Supervising Professor should discuss discrepancies with the student and have the student revise and re-submit the evaluation.)
	Supervising Professor completes Section IV, signs and dates Section V, and prepares a hardcopy of the form (prints the form) to be reviewed with the student.
	Student and Supervising Professor meet to review the completed evaluation and the student signs and dates Section V.
	Student arranges for a group meeting with the Supervising Committee.
	<i>Special circumstance:</i> If the Supervising Committee members and the student are unable to arrange a group meeting then:
	Student will meet individually with the Supervising Committee members.
	Supervising Professor submits a letter addressed to the MSCI Program Director that describes the special circumstances which prevented the group meeting. (The letter is to be forwarded with the Semi-annual Student Evaluation and Student Progress Report forms.)
	Student obtains the required signatures and dates on the Student Progress Report form during the group meeting. If there are special circumstances which prevented the group meeting signatures and date will be obtained during the individual meetings.
	Student delivers the signed and dated original forms/letter (listed below) to the MSCI Academic Coordinator.
	Semi-annual Student Evaluation form
	Student Progress Report form
	Supervising Professor's Letter of Explanation (if applicable)
The	e semi-annual student evaluations are due on or before 🗌 August 31 st and 🗌 February

Once a student has successfully met the research and manuscript requirements for graduation of the MSCI Program, no further semi-annual evaluations will be required.

28th of each academic year.

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI Program)

SEMI-ANNUAL STUDENT EVALUATION

STUDENT NAME:	REVIEW DATE:
STUDENT'S DEPARTMENT/DIVISION:	DEADLINE DATE: August 31 st aka Fall Semi-annual Evaluation (Evaluation Period: February-July) February 28 th aka Spring Semi-annual Evaluation (Evaluation Period: August-January)
STUDENT SUPERVISING PROFESSOR:	STUDENT SUPERVISING COMMITTEE: MSCI COGS Member:
	MSCI Graduate Faculty Member:
	UTHSCSA Faculty (Expertise Specific)

GOALS OF THE SEMI-ANNUAL STUDENT EVALUATION PROCESS ARE TO:

- A. Encourage a candid conversation between supervising professor(s) and student.
- B. Create a document for review by the student's supervising committee and by the MSCI Committee on Graduate Studies (COGS).
- C. Provide the student with a critique of past six months performance and accomplishments.
- D. Establish concrete goals to clarify performance expectations.
- E. Identify research and career development options.

Section I: Student Self Assessment

Brief Overview of student's research project and major accomplishments:

• Publications: Yes Yes No If yes, please list. (Include for each listing: PubMed Number; title; author(s); journal; and volume: page number.)

	[]	_	_
 Presentations at Local/National/International 			
Meetings:		Yes	No
If yes, please list. (Include for each listing:	: date; meeting, location, and		
Presentation title.)			

Seminar Presentations (Local/National/International):	🗌 Yes	🗌 No
If yes, please list. (Include for each listing: date, seminar, location, and Presentation title.)		
 Honors/Awards: If yes, please list. (Include for each listing: date, name/title, and description) 	Yes	🗌 No
 Intramural Funding: If yes, please list. (Include for each listing: submitted and/or funded applications.) 	Yes	🗌 No
 Extramural Funding: If yes, please list. (Include for each listing: submitted and/or funded applications.) 	Yes	🗌 No
Patents: If yes, please list.	I Yes	🗌 No
 New areas of research or technical expertise acquired: If yes, please describe. 	Yes	🗌 No
 Supervisory activity: If yes, please describe. (<i>i.e.</i>, oversight of graduate/undergraduate or sumr Student-include name, academic level, and project title.) 	Yes	🗌 No
 Teaching: If yes, please describe. (<i>i.e.</i>, lectures or lab sessions, and hours-include Department, course name, section title.) 	Yes	🗌 No
Clinical activity: If yes, please describe.	Yes	🗌 No

 Committee or other service activity: If yes, please describe. (Indicate if you held and office.) 	🗌 Yes	🗌 No
Other professional activity not identified above: If yes, please describe.	Yes	🗌 No
	- 	
 Other activities (community, etc.) with professional relevance: If yes, please describe. 	Yes	🗌 No
 Are there any obstacles to your research productivity?: If yes, please describe. 	Yes	🗌 No
Section II: Student Research and Other Training Plans Next Six (6) Months	for the	

• Research project and professional development goals:

• Anticipated publications (indicate project authors, titles, and journal):

• Anticipated meeting(s) or workshop(s) to be attended:

• Fellowship or other grant applications planned (indicate funding agency type of award, and application date):

• Other professional training (e.g., course work):

Section III: Student Career Goals

• Describe your long-term career goals:

	escribe what further research activity or other training is needed before it is appropriate to egin your job search:
• V	Vhen will your job search be initiated?:
	lease indicate if there are other issues that will affect your job search (<i>e.g.</i> , relocation onstraints, and international trainee with an assured position in home country):

Section IV: Supervising Professor's Assessment of Student's Performance

Rate performance in the following areas:

	Expectations Not Achieved	Meets Expectations	Exceeds Expectations	Distinguished	Cannot Assess
Overall Knowledge of: Project Literature Methods/Lab Techniques/Equipment					
Productivity/Quality of Work Lab Techniques					
Data: Management (<i>e.g.</i> , lab records) Analysis Interpretation					
Application of Data/Extension of Findings					
Teaching/Mentoring/Supervisory Skills					
Problem Solving/Critical Thinking Skills					
Innovation/Original Ideas					
Independence					
Communication: Oral Written [Revised: 06/12/2009]					

OVERALL ASSESSMENT

Would you recommend student for continuation in MSCI Program?	🗌 Yes	🗌 No	
What is the next level for this student? (<i>e.g.</i> , job, additional training in this la training in another lab)	b, addition	al	
		c	
What does the student need to do to reach the next level and what are the plans to achieve this translation?			

Additional comments:

Section V: Signatures

(Signatures below acknowledge review of this semi-annual evaluation.)

STUDENT NAME:	DATE:	

SUPERVISING PROFESSOR:

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI Program)

STUDENT PROGRESS REPORT

STUDENT NAME:		
STUDENT'S DEPARTMENT/DIVISION:		
SUPERVISING PROFESSOR:		,
]	Signature	Date
SUPERVISING COMMITTEE:		
MSCI COGS Committee Member	Signature	/ Date
MSCI Graduate Faculty Committee Member	Signature	/ Date
Expertise Specific UTHSCSA Faculty Committee Member	Signature	/ Date

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI) Program

Manuscript Approval Form

(Approval Signatures of Supervising Committee Required)

Student Name:					
Manuscript Title:					
Authors (complete listing in order of appearance):					
Journal:					
Submission Date:					
Signatures below affirm that the student's manuscript has been reviewed, approved and, if published, will represent a significant contribution to the literature.					
Supervising Professor	Signature	Date			
MSCI COGS Committee Member	Signature	Date			
MSCI Graduate Faculty Committee Member	Signature	Date			
Expertise Specific UTHSCSA Faculty Committee Member	Signature	Date			

The University of Texas Health Science Center at San Antonio IIMS/Clinical and Translational Research Education Office Master of Science in Clinical Investigation (MSCI) Program

Request to Amend MSCI Student Research Project			
(Signature Approval of Supervising Committee Required)			
Student Name:		Date:	
Request to Change:			
Supervising Profe	ssor		
(Current) Supervisi	ng Professor:		
(Proposed) Superv UTH:			
No , the propo	sed Supervising Professor	is a member of the MSCI Graduate Faculty. is not a member of the MSCI Graduate Faculty. <i>ill be considered separately by the MSCI COGS</i>	
Supervising Comr	nittee		
(Current) Supervisi		mber:	
I	MSCI Graduate Faculty Me	mber:	
Expertise Spe	ecific UTHSCSA Faculty Me	mber:	
(Proposed) Superv	MSCI COGS Mer Department/Div	nber: rision: dress:	
MS	CI Graduate Faculty Mer Department/Div UTHSCSA E-mail Ado	rision:	
Expertise Specif	ic UTHSCSA Faculty Mer Department/Div UTHSCSA E-mail Add	rision:	
Research Plan/Ti A request to change a	n approved research plan <u>mu</u>	<u>st</u> be accompanied by the revised research plan and a cover escribes the basis for the request.	
The signatures below		roval of the requested changes as listed above and/or attached.	
Note: The signatures below		Professor and/or the Supervising Committee that are proposed if ochange either of these.	

Supervising Professor	Signature	Date
MSCI COGS Supervising Committee Member	Signature	Date
Graduate Faculty Supervising Committee Member	Signature	Date
Expertise Specific UTHSCSA Faculty Committee Member	Signature	Date

Course Descriptions Master of Science in Clinical Investigation (MSCI)

MEDI 5070 Responsible Conduct of Patient-Oriented Clinical Research

2.0 Semester Credit Hours (SCH)

This interdisciplinary course is designed to train participants in the responsible conduct of patientoriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) delineate a history of hallmark abuses of humans enrolled in clinical research, (2) describe the evolution of national and international codes and regulations guiding inclusion of human subjects in clinical investigations, (3) list the elements of informed consent and describe procedures and precautions for enrolling special populations into clinical investigation, (4) write a consent form in understandable language, (5) recognize different forms of scientific misconduct, (6) describe the role and processes of a peer review board to judge violations in research ethics, (7) develop strategies for self-assessment and validation of scientific objectivity in one's own research, and (8) recognize ethical responsibilities the and consequences of whistle blowing.

MEDI 5071 Patient-Oriented Clinical Research Methods-1

2.0 Semester Credit Hours (SCH)

This interdisciplinary course is the first in a threesemester sequence designed to train participants in the conduct of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) define a research question, (2) effectively conduct a systematic review of the scientific literature, (3) design strategies for recruitment into a study, (4) delineate strategies for minimizing bias in crosssectional and retrospective studies, and (5) read and interpret research reports of cross-sectional and case control investigations.

MEDI 5072 Patient-Oriented Clinical Research Biostatistics 1

2.0 Semester Credit Hours (SCH)

This interdisciplinary course is the first in a twosemester sequence designed to train participants in the analysis and biostatistics of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) identify and summarize different categories of data; (2) set up and perform tests of hypotheses; (3) estimate sample sizes for survey and case-control studies; and (4) use statistical software packages to enter, summarize, graph, visualize, and analyze data.

MEDI 5073 Integrating Molecular Biology with Patient-Oriented Clinical Research

2.0 Semester Credit Hours (SCH)

This interdisciplinary course is designed to train participants on integrating molecular biology methods into patient-oriented clinical research. Students will have the opportunity to learn to: (1) appropriately use molecular terms in clinical investigation; (2) describe the events involved in protein synthesis; (3) describe the principles techniques involved in molecular (e.g., polymerase chain reactions, Southern blots); (4) identify the appropriate specimens, collection, and handling requirements for each molecular technique; (5) identify and correct common sources of error in performing molecular techniques; (6) cite examples of clinical applications of molecular techniques in clinical medicine; and (7) apply molecular techniques in the laboratory to specific clinical problems.

MEDI 5074 Data Management, Quality Control, and Regulatory Issues

2.0 Semester Credit Hours (SCH)

This interdisciplinary course is designed to train participants in the necessary data-management and quality-control procedures required for the conduct of patient-oriented clinical research. It consists of three segments:

Introduction to data management principles and standard practices:

Students will be able to describe trends and best practices in informatics for the organization of biomedical and health information. They will learn and practice:

- key data-management principles, and datamanagement habits of effective clinical investigators
- use of both spreadsheets and relational database management systems for the creation and management of traditional-scale datasets for translational research
- implementation of quality assurance systems for data collection and management for research projects.

Development of the following for the students' own mentored research:

- design of a relational database using Microsoft Office Access 2007 –including qualityassurance and -control procedures;
- a data dictionary for the project, and a manual of operations describing staff training requirements for data collection, and quality control procedures;
- a budget for the data management elements of the project.

Introduction to bioinformatics:

In addition, students will:

- be able to discuss the role of bioinformatics in dealing with high-dimension datasets, and current strategies for dealing with massive datasets, such as are required for genetic and proteomic data;
- be introduced to bioinformatics specialists both within and outside the institution – with whom collaborations can develop for the design, development, and implementation of future research projects and data management systems;
- be able to describe the essential functions of the electronic health record, barriers to its use, and the impact of health information technology standards on interoperability of clinical systems, including health IT messaging.

MEDI 5075 Scientific Communication

2.0 Semester Credit Hour (SCH)

This interdisciplinary course is designed to train participants to write effectively in all aspects of conducting patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) recognize and avoid errors in grammar, punctuation, and usage that are common in scientific writing; (2) construct units of writing whose structure, style, and logical continuity allows instant and clear comprehension; (3) construct concise, informative titles; (4) develop clear, comprehensive, abstracts for papers and grant proposals; (5) construct complete, wellrationalized sets of specific aims for grant proposals; and (6) effectively apply the 4-Point Rule (What is the question? How did we approach it? What happened? What does it mean?) to all forms of scientific writing.

MEDI 5076 Introduction to Informatics

1.0 Semester Credit Hour (SCH) (elective course)

This *elective* course is designed to serve the interests of practicing clinicians who are pursuing a career in clinical investigations. In this course, students will be introduced to widely available tools, online and UT Health Science Center at San Antonio resources. They will become familiar with some of the guiding principles and current issues in informatics. The students will occasionally participate in practicum sessions that will give them hands on experience with the resources discussed in the class as well have an opportunity to discuss Ethical, Social, and Legal Issues (ESLI) surrounding informatics today.

MEDI 5077 Practicum in Translational Science

1.0–3.0 Semester Credit Hours (SCH) (elective course)

Prerequisite: Consent of the Course Director

This *elective* course provides an opportunity for participation in unique clinical and translational research activities that are highly individualized for each student on the basis of prior experience and research interests.

MEDI 6060 Patient-Oriented Clinical Research Methods-2

2.0 Semester Credit Hours (SCH)

Prerequisite: Patient-Oriented Clinical Research Methods-1

This interdisciplinary course is the second in a three-semester sequence designed to train participants in the conduct of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) define criteria for inferring causation from observational studies; (2) design strategies for subject retention in a prospective study; (3) design strategies for monitoring progress in a randomized control trial; (4) delineate strategies for minimizing bias in cohort studies and randomized control trials; (5) compare and contrast the uses, strengths, and weaknesses of different clinical trial designs; (6) read and interpret research reports of cohort studies and randomized control trials; and (7) describe the steps in conducting a meta-analysis.

MEDI 6061 Patient-Oriented Clinical Research Biostatistics 2

2.0 Semester Credit Hours (SCH)

Prerequisite: Patient-Oriented Clinical Research Biostatistics - 1

This interdisciplinary course is the second in a two-semester sequence designed to train participants in the biostatistical analysis of patientoriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) perform a two-way analysis of variance and explain the results; (2) perform survival analysis; (3) compare and contrast the purpose and characteristics of different forms of interventional trials; and (4) plan the sample size, analysis, and stopping rules of a randomized clinical trial.

MEDI 6064 Grantsmanship and Peer Review

1.0 Semester Credit Hour (SCH) (elective course)

The purpose of this *elective* course is to provide an overview of the peer review process for research proposals as well as the essential components of grant management. Lecture and assignment topics will include: (1) Funding agencies, missions, deadlines, and instructions, (2) Institutional Grantsmanship Issues, (3) National Institutes of Health (NIH) organization (Institutes, Councils, Centers, and Budgets), (4) NIH Awards Sections. and Study (5) Process and communications with the NIH, (6) Interpreting and responding to written critiques, (7) Mock study section meeting, and (8) Grantsmanship after funding.

MEDI 6065 Health Services Research

2.0 Semester Credit Hours (SCH)

Prerequisite: Patient-Oriented Clinical Research Methods-1 and Patient-Oriented Clinical Research Methods-2

This course focuses on concepts and methods used in research focusing on health care quality, utilization, access, and safety. The seminar will utilize skills-based learning, small group activities, and outside assignments. By the end of the course, candidates will be required to:

- Articulate underlying core concepts
- Describe basic methods used in health services research
- Identify relevant databases and data sources for health services research
- Critically appraise and interpret published reports of health services research
- Discuss current issues in HSR
- Understand how to incorporate health services concepts, methods, or tools, into current research

MEDI 6066 Instrument Validation and Development

1.0 Semester Credit Hour (SCH) (elective course)

This course introduces methods used to develop and evaluate self-report measures. The seminar is built on classical test theory with a focus on the practice of creative surveys. Participants should be able to: (1) estimate various forms of reliability; (2) demonstrate various forms of validity evidence; and (3) explain how statistical analyses may be used to inform the validation process.

MEDI 6067 Genetics and Genetic Epidemiology

1.0 Semester Credit Hour (SCH) (elective course)

The main objective of this *elective* course is to familiarize students with current concepts and methods used in patient-oriented genetic studies. The class is oriented toward all health professionals - no prior genetics coursework is required. Topics include a review of the human genome structure followed by lectures and discussion on current research areas such as genetic epidemiologic studies, applications of microarray technologies, and pharmacogenomics. By the end of the course, candidates will be able to 1) Articulate basic concepts and current analytical methods used for human genetics research, 2) Identify and use relevant databases and data sources for genetics research, 3) Interpret the literature and discuss current issues of human genetics research, and 4) Understand the potential and current limits of personalized medicine.

MEDI 6068 Cross Cultural Adaptation of Research Instruments

1.0 Semester Credit Hour (SCH) (elective course)

This course introduces students to the concept of cross-cultural equivalence of research instruments – a prerequisite for making valid comparisons across two or more ethnic groups – and the process of cross-cultural adaptation used to achieve this equivalence. Students will learn the multiple steps necessary to successfully cross-culturally adapt research instruments and how to assure content, semantic, technical, conceptual, and criterion equivalence of individual items and scales. A number of instruments used in cross-cultural research will be reviewed and critiqued with regard to their cross-cultural equivalence.

MEDI 6097 Research

1.0 - 3.0 Semester Credit Hours (SCH)

The Research Course is set up for the student to conduct their Mentored Research Project with their faculty advisor. This time is to be spent directly working on the project and includes, but is not limited to, writing consent forms, collecting data, analyzing data, and preparing papers and/or a thesis. After MSCI COGS approval of the research project, students will take three semester credit hours of research during each semester of the Master of Science in Clinical Investigation Degree Program.

MEDI 6100 Practicum in IACUC Procedures

1.0 Semester Credit Hour (SCH) (elective course)

Prerequisite: Consent of the Course Director

This *elective* course presents an in-depth introduction to the institutional program that provides oversight and regular review of projects that involve the care and use of animals. This includes consideration of the operational procedures of the Institutional Animal Care and Use Committee (IACUC) of the University of Texas Health Science Center – San Antonio. Course objectives are achieved through a combination of readings, monthly attendance at selected IACUC meetings, and discussions with faculty.

MEDI 6101 Topics in Translational Science

1.0 Semester Credit Hour (SCH) (elective course)

Prerequisite: Consent of the Course Director

This *elective* course addresses selected topics in translational science through a series of lectures, assigned readings, literature reviews, class presentations, and discussions with faculty

MEDI 6102 Practicum in IRB Procedures

1.0 Semester Credit Hour (SCH) (elective course)

Prerequisite: Consent of the Course Director

This *elective* course presents an in-depth introduction to the institutional program that provides oversight and regular review of research projects that involve human subjects. This includes consideration of the operational procedures of the multiple Institutional Review Boards (IRB) of the University of Texas Health Science Center – San Antonio. Course objectives are achieved through a combination of readings, monthly attendance at selected IRB meetings, and discussions with faculty.

MEDI 6103 Selected Topics in Advanced Research Ethics

1.0 Semester Credit Hour (SCH) (elective course)

Prerequisite: Consent of the Course Director

This *elective* course provides an in-depth understanding of a selected topic in research ethics. Students work independently to develop a detailed literature review specific to an area of research and are required to prepare a manuscript describing the results. Regular meetings with the Course Director will review progress towards course goals.

MSCI Contact Information

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This educational program is supported in part by a grant provided by the National Center for Research Resources of the National Institutes of Health (U54 RR024387)

Responsible Conduct of Patient-Oriented Clinical Research 🔹 Patient-Oriented Clinical Research Methods 🔹 Patient-Oriented Clinical Research Biostatistics • Integrating Molecular Biology with Patient-Oriented Clinical Research • Data Management, Quality Control, and Regulatory Issues • Grantsmanship and Peer Review • Health Services Research • Instrument Validation and Development • Genetics and Genetic Epidemiology • Cross Cultural Adaptation of Research Instruments • Responsible Conduct of Patient-Oriented Clinical Research • Patient-Oriented Clinical Research Methods • Patient-Oriented Clinical Research Biostatistics • Integrating Molecular Biology with Patient-Oriented Clinical Research

Data Management, Quality Control, and Regulatory Issues Grantsmanship and Peer Review

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 Integrating Molecular Biology with Patient-Oriented Clinical Research Data Management, Quality Control, and Regulatory Issues • Grantsmanship and Peer Review • Health Services Research • Instrument Validation and Development • Genetics and Genetic Epidemiology • Cross Cultural Adaptation of Research Instruments • Responsible Conduct of Patient-Oriented Clinical Research

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Integrating Molecular Biology with Patient-Oriented Clinical Research

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