2007-2008
Program, Policies, and Guidelines

Master of Science in Clinical Investigation (MSCI)

Program, Policies, and Guidelines

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Appendices

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 UTHSCSA for the optimal training of future clinical and translational investigators.
- Provide fundamental curricular activities and valuable training opportunities in clinical and translational research to UTHSCSA students, postdoctoral trainees, and faculty from the Schools of Medicine, Nursing, Dentistry, Allied Health, and Graduate School of Biomedical Sciences as well as from local organizations that are partnered with UTHSCSA.

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* research mentor, research project, and advisory committee
- 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/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 health-related discipline including medical or dental school 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**, preferably three, attesting to the applicant's readiness for graduate level studies in clinical investigation. For residents or fellows in an approved UTHSCSA residency or fellowship program, one of these letters should be from the departmental Chairman with the inclusion of a statement indicating the availability and approval of release time for the completion of MSCI educational and research activities.
6. A **Personal Statement** that 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.

Application to the MSCI Program

Applications to the MSCI program are submitted through the UTHSCSA Graduate School of Biomedical Sciences (GSBS) and reviewed by the MSCI Committee on Graduate Studies (COGS). Application for admission into the MSCI program and the GSBS requires online completion and submission of the **Texas Common Application**. Details regarding the MSCI application process as well as an **application checklist** are available on the **MSCI web site**.

The MSCI program has an open application policy and will accept applications for admission at any time. The MSCI Admissions Committee will review each application individually. The Committee will consider the applicant's undergraduate and graduate course work and degree(s), scores on the GRE and TOEFL (if applicable) tests, research experience, letters of recommendation, and personal statement provided with the application. Research experience is not required but may be beneficial. After review by the MSCI Admissions Committee, applications will then be considered at a routine MSCI COGS meeting; applicants will be immediately notified of the decision. The Committee offers admission to the most highly qualified applicants regardless of ethnicity, gender, age, sexual orientation, nation of origin, or disability. **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.

An approved research mentor, research project, and advisory committee will be required for the successful completion of the MSCI, however, details of these components is **not** a prerequisite in consideration for admission into the program. *For applicants who anticipate completion of the requirements for graduation within 2 years*, it is highly recommended that the research mentor and 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 (Special) 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 research project and Supervising Professor.

After acceptance into this graduate program as a candidate for the MSCI degree, students may complete the requirements for graduation while enrolled as either a full-time or part-time student (see below).

Pathways of Student Participation 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 Supervising Professor and a mentored research project is identified and approved by the MSCI COGS (typically prior to admission 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) credit hours per 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 become a full-time student upon admission, students must have an approved Supervising Professor and mentored research project at the time of application into the program*. If the research project is approved and undertaken at the time of acceptance in the MSCI program, 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. Earning the MSCI degree as a part-time student will usually require 3-4 years.

UTHSCSA Faculty and Staff as Students in the MSCI program. UTHSCSA Faculty and Staff may apply for admission in the MSCI Program and enroll in coursework only as a *part-time student*. The amount of course work taken by UTHSCSA Faculty and Staff in a given semester is subject to the 'quantity of work' rules set out in the **Graduate School Catalog** and the UTHSCSA **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 UTHSCSA. As a consequence, denying access to the MSCI Courses to foreign nationals (persons at UTHSCSA

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 UTHSCSA.

2. They may enroll in up to four credit hours of didactic course work per semester. These four credits will be in formal lecture and seminar courses which are 'incident to' the purpose of the visa. Four credit hours is less than half of the semester credit hours considered to constitute full-time enrollment in the UTHSCSA Graduate School of Biomedical Sciences. Thus, these individuals will be part-time graduate students.

3. They may enroll in research credits under the supervision of their research mentors. 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 (COGS), Program Director, and the individual's Research Mentor. The number of research credits allowed per semester will be determined on a case-by-case 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 creatinfsg a pathway by which foreign nationals may participate in clinical research education at UTHSCSA.

Foreign nationals who seek admission to the MSCI Program as full-time students may do so under an F-2 Student Visa.

Non-Degree Seeking Students in the GSBS. Special Students (non-degree seeking students) may enroll in MSCI-sponsored courses for credit from the GSBS *without* matriculation (entry) into the MSCI program. For those who are not already matriculated into other GSBS graduate programs, an **application form** (*Application for Admission* to the GSBS) must be submitted to the GSBS for approval by the Dean [this would also include students who are matriculated in other HSC 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 Dean's office).

Course credit earned as a non-degree seeking student can be applied towards an MSCI degree following formal application/acceptance into the MSCI Program. An MS Degree in Clinical Investigation **cannot** be obtained as a non-degree seeking student. Note that there is a limit of 4 years of enrollment as a non-degree seeking student in the GSBS. Additional details about Special Students are available at the **UTHSCSA GSBS website.**

Specific Degree Requirements

Research Project. A Supervising Professor (primary research mentor), Supervising (Mentoring) 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 Requirement

A student must identify a Supervising Professor (Primary Mentor), establish a Supervising (Mentoring) Committee, and select a research area of interest. Each of these must be approved by the MSCI Committee on Graduate Studies (COGS) as outlined below.

Supervising Professor (Primary Mentor). The Supervising Professor (Primary Mentor) will oversee all aspects of the student research project and must be a member of the MSCI Graduate Faculty (designated as the MSCI Programmatic Graduate Faculty; all Graduate Faculty are individually approved by the Graduate School of Biomedical Sciences). In the event that a student identifies a Supervising Professor who is not a member of the MSCI Graduate Faculty, the COGS will separately assess the qualifications of that individual for recommendation for appointment to the MSCI Graduate Faculty (see below). Requests for consideration of appointment to the MSCI Graduate Faculty may be considered 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.

Supervising (Mentoring) Committee. The student, with the help of his/her Supervising Professor, will choose a Supervising (Mentoring) Committee. It is recommended that the committee be established by the beginning of the Fall semester of the first year for full-time students, and the Spring Semester of the first year for part-time students. The 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 additional faculty of the HSC 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.

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. The written proposal should not exceed six double-spaced typewritten pages and should consist of:

(A) Hypothesis
(B) Specific Aims
(C) Significance (with background and rationale)
(D) Experimental Design
(E) References (*not included in the 6 page limit*)

After approval of the written research proposal by the Supervising Committee, the proposal shall be forwarded to the COGS for approval. Once the research project is approved, the student will begin participating in research activities under the direction of the Supervising Professor and register to receive course credit (*MSCI 6097 - Research in Clinical Investigation*). A grade of "Unsatisfactory" (U) for 50% or more of course credit in research (semester hours) 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 research project, Supervising Professor (Primary Mentor), or Supervising (Mentoring) Committee after approval by the MSCI Committee on Graduate Studies (COGS), the 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 Chairman of the MSCI COGS together with a *Request to Amend MSCI Student Research Program* Form and a description of the basis for the request to change the Supervising Professor.

Changing a Supervising Committee. Any change in membership in an already approved Supervising Committee requires review and approval by the MSCI COGS. This request should be submitted in writing to the Chairman of the MSCI COGS together with a *Request to Amend MSCI Student Research Program* Form and a description of the basis for the request to change the membership of the Supervising Committee.

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 Committee prior to consideration by the MSCI COGS. The written request to change the research project must be submitted to the Chairman of the MSCI COGS and should include:

- Copy of 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
- *Request to Amend MSCI Student Research Program* Form

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 should be completed and signed/dated by all members of the 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) of manuscript submission/acceptance
    - The completed *Manuscript Approval Form* of the MSCI Student Supervising Committee

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

Required Courses. Masters students in Clinical Investigation must successfully complete the following didactic courses.

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

Exemptions to the requirement for the 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 Chairman of the MSCI COGS 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.

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 approval of the Supervising Professor and research project by the MSCI COGS, students may enroll in:

MEDI 6097 (3 hours) –Research

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 Chairman of the MSCI COGS and will be considered on a case-by-case basis. A written request for exemption must be submitted to the Chairman of the MSCI COGS (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 (1 hour) – Grantsmanship and Peer Review
MEDI 6066 (1 hour) – Instrument Development and Validation
MEDI 6067 (1 hour) – Genetics Primer for Patient Oriented Research
MEDI 6068 (1 hour) – Cross Cultural Adaptation of Research Instruments

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 all MSCI-sponsored 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 Program.

***Class Attendance and Makeup Policy*.** The UTHSCSA MSCI faculty believes 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**

Makeups. It is possible to makeup for absences (both excused and unexcused). Makeup of absences is allowed at the discretion of the Course Director.

Other Requirements of the MSCI Program

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 UTHSCSA bookstore with a student ID)
- Intercooled Stata, *vs* 9.0, **http://www.stata.com/order/new/edu/gradplans/gp-campus.html**

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

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

Semi-Annual Evaluation of Student Progress. MSCI students with an approved research project shall prepare a semi-annual written report of progress for consideration by their Supervising

(Mentoring) Committee. The completed *Semi-Annual MSCI Student Evaluation Form* and the *Student Progress Form* of the MSCI Supervising Committee must then be submitted the Chair of the MSCI COGS as described below.

Semi-Annual Student Evaluation

After a mentored research project has been approved by the MSCI COGS, a student will be evaluated by the Supervising Professor (Primary Mentor) and Supervising (Mentoring) Committee at least once every six months throughout the remainder of their enrollment in the MSCI Program. To accomplish this objective, 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 Primary Mentor) 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 previous meeting with the Supervising Committee, as well as plans for the future towards completion of the requirements in fulfillment of MSCI. If requested, the student may be asked to leave the meeting during Committee deliberations. The 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 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 *MSCI Semi-Annual Student Evaluation* 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 committee's decisions and must inform any member not in attendance of all decisions of the Committee regarding the outcome of student evaluation including research progress and future work. A copy of this memorandum should be provided to the Chair of MSCI COGS together with a copy of the *MSCI Semi-Annual MSCI Student Evaluation* Form and the S*tudent Progress Report* Form of the Supervising Committee 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 provided 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 and Professionalism Policy

The MSCI program expects all students to exhibit the highest standards of conduct, honesty, and professionalism. Academic misconduct includes any activities that tend to undermine the academic integrity of the institution. The university may discipline a student for academic misconduct as outlined in the UTHSCSA Student **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 university-related activities including conferences and off-campus 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.

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 of the Supervising Committee; the COGS Chair shall so indicate by signature on GSBS *Form 41*. This form and the *Report to the Graduate Faculty Council* (GFC) of the Graduate School of Biomedical Sciences (GSBS) will then be submitted the GFC for their consideration.

Time-to-Masters Degree. It is expected that that the MSCI degree 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 part-time

student has not graduated in 4 years), the 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.

MSCI (Programmatic) Graduate Faculty

The MSCI COGS assesses the qualifications of each individual prior to recommendation to the Dean of the Graduate School of Biomedical Sciences (GSBS) for their appointment to the MSCI Programmatic Graduate Faculty. 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 five (5) 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.

Appendices

T*ypical 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 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 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

Graduate Faculty
Master of Science in Clinical Investigation (MSCI)

Hanna Abboud, MD
Medicine/Nephrology

Nedal Arar,PhD
Medicine/Nephrology

Robert Badgett, MD
Medicine

Jacques Baillargeon, PhD
Pediatrics

Carrie Jo Braden, RN,PhD
Nursing

Robin Brey, MD
Medicine/Neurology

John Brown, PhD
Community.Dentistry

Robert Clark, MD
Medicine

David Cochran, DDS, PhD
Periodontics

Laurel Copeland, PhD
Psychiatry

John Cornell, PhD
Medicine/Geriatrics

Ralph DeFronzo, MD
Medicine/Diabetes

Agustin Escalante, MD
Medicine/Rheumatology

Robert Ferrer, MD
Family and Community Medicine

Sharon Fowler, MPH
Medicine/Clinical Epidemiology

Goutam Ghosh-Choudhury, PhD
Medicine/Nephrology

Helen Hazuda, PhD
Medicine/Clinical Epidemiology

Angela Khan
Institutional Review Board

George Kudolo, PhD
Clinical Laboratory Sciences

Valerie Lawrence, MD
Medicine

Robin Leach, PhD
Cellular and Structural Biology

Donna Lehman, PhD
Medicine/Clinical Epidemiology

Michael Lichtenstein, MD
Medicine/Geriatrics/GCRC

Bettie Sue Masters, PhD
Biochemistry

Shirlyn McKenzie, PhD
Clinical Lab Sciences

Linda McManus, PhD
Pathology

Joel Michalek, PhD
Biostatistics and Epidemiology

Eric Mortensen, MD
Medicine

Polly Noel, PhD
Medicine

Steven Owen, PhD
Medicine/Epidemiology

Michael Parchman, MD
Family and Community Medicine

Jimmy Perkins, PhD
School of Public Health, UT-Houston

Brad Pollock, PhD
Biostatics and Epidemiology

Thomas Prihoda, PhD
Pathology

Jacqueline Pugh, MD
Medicine

Mary Jo Pugh, PhD
Medicine

John Schoolfield, MS
Academic Information Services

John Rugh, PhD
Orthodontics

Paula Shireman, MD
Surgery/Vascular

Linda Smith, PhD
Clinical Lab Sciences

Steven Schenker, MD
Medicine/Gastroenterology

Ian Thompson, MD
Urology

Z. Dave Sharp, PhD
Molecular Medicine

Committee on Graduate Studies (COGS)
Master of Science in Clinical Investigation (MSCI)

MSCI COGS Chairman
Michael Lichtenstein, MD

Carrie Jo Braden, RN,PhD
Nursing

John Brown, PhD
Community.Dentistry

Robert Clark, MD
Medicine

John Cornell, PhD
Medicine/Geriatrics

Sharon Fowler, MPH
Medicine/Clinical Epidemiology

Goutam Ghosh-Choudhury, PhD
Medicine/Nephrology

Helen Hazuda, PhD
Medicine/Clinical Epidemiology

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Biostatistics and Epidemiology

Steven Schenker, MD
Medicine/Gastroenterology

John Schoolfield, MS
Academic Information Services

Linda Smith, PhD
Clinical Lab Sciences

Z. Dave Sharp, PhD
Molecular Medicine

Instructions for Completion of the
Semi-annual MSCI Student Evaluation

Master of Science in Clinical Investigation (MSCI)

The University of Texas Health Science Center at San Antonio

First, the student should complete Sections 1-3 of this document (the *MSCI Semi-annual Student Evaluation Form*) and forward an electronic copy to the Primary Mentor. The Primary Mentor should complete Section 4 after reading/approving all student entries in Sections 1-3; approval is documented by providing initials in the boxes at the beginning of each Section. The student and mentor should then meet to discuss the completed form that should be signed and dated by both the student and the mentor.

Second, the student is responsible for circulating the completed (signed) *MSCI Semi-Annual Student Evaluation Form* to all members of his/her Supervising Committee as well as for scheduling a meeting with this group. Optimally, this should be a meeting of the entire group in order to gain the benefit of a group discussion of student progress. However, under special circumstances, the student may meet individually with each member of their Supervising Committee; in this case, a memo should be provided by the Primary Mentor to describe the special circumstances which prevent a group meeting. Signatures of all members of the Student Supervising Committee should be obtained on the *Student Progress Report Form* of the MSCI Student Supervising Committee (the last page of this document).

Finally, the original (signed) *Student Progress Report Form* of the MSCI Student Supervising Committee together with the original (signed) *MSCI Semi-Annual Student Evaluation Form* should be submitted to the Academic Coordinator of the MSCI Program. The Student Advisory Subcommittee of the MSCI COGS will then consider these documents.

MSCI SEMI-ANNUAL STUDENT EVALUATION FORM

Master of Science in Clinical Investigation (MSCI)

The University of Texas Health Science Center

Name:_____ Review Date:_____

Department:_____

Primary Mentor:_____ Supervising Committee:

_____

_____

_____

Goals of the semi-annual review process are to:

A. Encourage a candid conversation between research mentor(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.

Sections 1-3 to be completed by the student and read/initialed by the mentor(s) in the boxes provided.
Sections 4-5 to be completed by the Primary Mentor. This form must be signed by student and mentor.

☐ **Section 1. Student Self-Assessment**

Brief overview of your research project and major accomplishments in the past 6 months (~1/2 page):

☐ **Section 1 (cont.). Student Self-Assessment** (use additional sheets as necessary)

	Yes	No
• Publications in past 6 months (number =____) If yes, please list (with complete detail of authors, title, journal, pagination)	☐	☐
• Presentations at Local/National/International Meetings: If yes, please list (meeting, date, presentation title):	☐	☐
• Seminar Presentations (Local/National/International): If yes, please list (where, when, presentation title):	☐	☐
• Honors/Awards: If yes, please describe:	☐	☐
• Intra- or Extramural Funding If yes, please list: (include submitted and/or funded applications)	☐	☐
• Patents: If yes, please list:	☐	☐
• New areas of research or technical expertise acquired in past 6 months: If yes, please describe:	☐	☐
• Supervisory activity: If yes, please describe, *i.e*., oversight of graduate/undergraduate or summer student (name, academic level, project title):	☐	☐
• Teaching If yes, please describe, *i.e*., lectures or lab sessions, amount (department, course name, section title):	☐	☐
• Clinical activity (if applicable): If yes, please describe:	☐	☐
• Committee or other service activity (indicate if you held an office): If yes, please describe:	☐	☐
• Other professional activities not identified above: If yes, please describe:	☐	☐
• Other activities (community, etc.) with professional relevance: If yes, please describe:	☐	☐
• Are there any obstacles to your research productivity? If yes, please describe.	☐	☐

☐ **Section 2. Student Research and Other Training Plans for the Coming 6 Months**

• Research project and professional development goals (brief paragraph):

• Anticipated publications (indicate projected 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 3. Student Career Goals**

- Describe your long-term career goals?

- Describe what further research activity or other training is needed before it is appropriate to begin your job search?

- When will your job search be initiated?

- Please indicate if there are other issues that will affect your job search (*e.g.*, relocation constraints, an international trainee with an assured position in home country):

Section 4. Primary Mentor'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 (*e.g*. 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	☐	☐	☐	☐	☐

OVERALL ASSESSMENT

Would you recommend student for continuation? Yes ☐ No ☐

What is the next level for this student (*e.g*., job, additional training in this lab, additional training in another lab)?

What does the student need to do to reach the next level? What are plans to achieve this transition?

Additional comments (additional pages may be added as necessary):

Section 5. Signatures. Signed by both student and mentor to acknowledge this semi-annual evaluation.

Student_____ Date_____

Primary Mentor_____ Date_____

Student Progress Report Form
MSCI Supervising Committee

Master of Science in Clinical Investigation (MSCI)
The University of Texas Health Science Center

Student Name: _____

Department: _____

Signature / Date

Primary Mentor: _____ _____/_____
(printed)

Supervising Committee:

Signature / Date

_____ _____/_____
(printed)

_____ _____/_____
(printed)

_____ _____/_____
(printed)

Manuscript Approval Form
MSCI Supervising Committee

Master of Science in Clinical Investigation (MSCI)

The University of Texas Health Science Center at San Antonio

Student Name:_____
(printed

Manuscript Title: _____

_____

_____

Authors (complete listing in order of appearance): _____

_____

_____

Journal:_____

Submission Date:_____

Signatures below affirm that the student manuscript has been reviewed/approved and, if published, will represent a significant contribution to the literature.

Signature / Date

Primary Mentor:_____ _____/_____
(printed)

Supervising Committee:

Signature / Date

_____ _____/_____
(printed)

_____ _____/_____
(printed)

_____ _____/_____
(printed)

Request to Amend MSCI Student Research Program

Master of Science in Clinical Investigation (MSCI)

The University of Texas Health Science Center at San Antonio

Student Name:_____ Date_____
(print)

Request to change:

☐ **Supervising Professor**

Current Supervising Professor: _____
(print)

Proposed Supervising Professor: _____
(print)

Is the proposed Supervising Professor a member of the MSCI Graduate Faculty?

☐ yes ☐ no

Note that if the proposed Supervising Professor is not a member of the MSCI Graduate Faculty, this appointment will be separately considered by the MSCI COGS.

☐ **Supervising Committee**

Current Supervising Committee: _____
(please print names)
_____
_____
_____

Proposed Supervising Committee: _____
(please print names)
_____
_____
_____

☐ **Research Project**

A request to change an approved research project should be accompanied by a copy of the revised research proposal.

This completed form together with a written description of the basis for the requested change(s) should be submitted to the Chairman of the MSCI COGS.

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 patient-oriented 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 the ethical responsibilities 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 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 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 cross-sectional 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 three-semester 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 involved in molecular techniques (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 design and creation of 1) data management systems which incorporate quality control strategies, 2) data documentation tools, and 3) information security policies required for the conduct of patient-oriented clinical research. It also reviews basic principles of staff training and budget design necessary to support data management systems and quality control.

An overarching goal and focus of the course is to help students move beyond the data management limitations of working exclusively with spreadsheets, such as Microsoft Office Excel, to be able to work within the more powerful environment of relational database management systems. Students will have the opportunity to learn - and by the end of the course will be required – to: (1) develop a relational database management system for their current or future mentored research project, using Microsoft Office Access; (2) develop data dictionaries and other documentation approaches to increase data security; and (3) develop appropriate information security policies and practices, including the following: a) storing databases on the most secure devices available (e.g., using departmental servers when possible; otherwise, using desktop PCs with appropriate firewalls and access restrictions; and encrypting any PHI which must be stored on mobile storage devices). The impact of these approaches on the data management requirements within research budgets is also emphasized in the course.

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, well-rationalized 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 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 three-semester 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) perform a two-way Analysis of Variance and explain the results; (2) prepare a life table and graph the results; (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)

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. Topics include: (1) Funding agencies/missions/deadlines/instructions, (2) Institutional Grantsmanship Issues, (3) National Institutes of Health (NIH) organization (Institutes/Councils/Centers/Budgets), (4) NIH Awards and Study Sections, (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
Patient-Oriented Clinical Research Methods-2

This course focuses on concepts and methods used in research focusing on health care quality, utilization, access, costs, 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
- Incorporate health services concepts, methods, or tools, into current research

MEDI 6066 Instrument Validation and Development
1.0 Semester Credit Hours (SCH)

MEDI 6067 Genetics and Genetic Epidemiology
1.0 Semester Credit Hours (SCH)

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 Hours (SCH)

MEDI 6097 Research
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. Students will take three semester credit hours of research during each semester of the Master of Science in Clinical Investigation Degree Program.