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 • Grant Annual Control of Research • Instrument Validation and Development • Genetics and Genetic Epidemiology • Cross Currur Acaptation of Research Instruments • Practicum in Translational Science Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics in Translational Science • Practicum i GACUC Procedures • Topics • Topi ures • Topics in Translational 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

Practicum in Translational Science Introduction to Translational Science • Practicum in IACUC Procedures • Topics in Translational Science • Practicum in IRB Procedures

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Responsible Conduct of Patient-Oriented Clinical Research

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Patient-Oriented Clinical Research Methods

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MSCI-TS Program policies and guidelines are in compliance with those established by the UT System (http://www.utsystem.edu/) Board of Regents (http://www.utsystem.edu/offices/board-regents/regents-rules-and-regulations), The UTHSCSA (http://www.uthscsa.edu/hop2000/), and the Graduate School of Biomedical Sciences (http://gsbs.uthscsa.edu/). The *Catalog* (http://catalog.uthscsa.edu/) of The UT Health San Antonio provides general information and regulations that relate to students. In the event of discrepancies between MSCI-TS Program policies/guidelines and those established by UT governing components, those described by the governing components will prevail.

The policies of the MSCI-TS Program are regularly reviewed and updated; therefore, this copy may not be the most current. Current policies are provided in the MSCI-TS Handbook that is electronically available at the MSCI-TS website: http://ims.uthscsa.edu/ed_msci_handbook.html



Master of Science in Clinical Investigation and Translational Science

IIMS/Office of Research Education and Mentoring UT Health San Antonio 7703 Floyd Curl Drive San Antonio, Texas 78229-3900 210-567-4304 (voice) E-mail: <u>Machuca@uthscsa.edu</u>

The UTHSCSA is accredited by the Commission on Colleges of the Southern Association of Colleges and Schools (<u>http://www.sacscoc.org/</u>) (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 and Translational Science

Program, Policies, and Guidelines

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UT Health San Antonio GRADUATE SCHOOL OF BIOMEDICAL SCIENCES

Master of Science in Clinical Investigation and Translational Science (MSCI-TS) Program

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-TS Program are to:

- Support the intellectual environment at UT Health San Antonio (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 UT Health San Antonio students, postdoctoral trainees, and faculty from the Schools of Medicine, Nursing, Dentistry, Health Professions, and Graduate School of Biomedical Sciences (GSBS) as well as from local organizations that are partnered with UT Health San Antonio.

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

- Participation and successful completion of required didactic coursework
- Establishment of an approved Supervising Professor, Research Supervising Committee (RSC) and research project proposal
- 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 and Translational Science (MSCI-TS)

Applicant Eligibility 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 an U.S. equivalent degree and training at a foreign institution as determined by an evaluation from the Educational Credential Evaluators, Inc. (ECE) or the World Education Services, Inc. (WES) of the foreign transcripts.
- 2. A **Grade Point Average** (GPA) no lower than a 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**). Scores on GRE tests taken more than five years prior to the date of application will not be accepted.
 - a. **Exemption:** Applicants who have completed a graduate degree in a health-related discipline or an U.S. equivalent degree (if awarded from a foreign institution, in a health-related discipline) (MD, DDS, RN, or PhD) are exempted from the requirement to complete the GRE.
- 4. A minimum score of 560 on the paper version or 68 on the internet version of the Test of English as a Foreign Language (**TOEFL**) or 6.5 on the academic version of the International English Language Testing System (**IELTS**) for applicants from countries where English is not the native language. Scores on the TOEFL and IELTS (academic version) tests taken more than two years prior to the date of enrollment will not be accepted.

Applicant Documentation Requirements

- 1. **Completed and submitted GSBS online application.** The GSBS online application can be found on the <u>GSBS homepage</u>.
- 2. Official transcripts from ALL colleges and universities attended.
- 3. **Course by Course Translation of ALL foreign** transcripts to include GPA and U.S. degree equivalency by the ECE or WES agencies.
- 4. **Official GRE scores** taken within the past five (5) years.
- 5. **Official TOEFL or IELTS (academic version) scores** taken within the past two (2) years for foreign national applicants.
- 6. **Three (3) Letters of Recommendation** attesting to the applicant's readiness for graduate level studies in clinical investigation and translational science. These letters of recommendation should be uploaded by the individual recommenders who will receive an e-mail from the EMBARK online application system with a link to the Recommendation Form.
 - **Residents** or **fellows** in an approved UT Health San Antonio residency or fellowship program are required to submit one (1) of the three (3) letters from the departmental chair with a statement indicating the availability and approval of release time for the completion of the MSCI-TS educational and research activities.

- **Staff** employed at UT Health San Antonio are required to submit one (1) of the three (3) letters from their authorized supervisor with a statement indicating the availability and approval of release time for the completion of the MSCI-TS educational and research activities.
- **Faculty** (*non-tenured only*) at UT Health San Antonio are required to submit one (1) of the three (3) letters from the Chair of their department. In addition, the Chair's letter must have the approval signatures of both the Dean of the school that houses the department and the President of UT Health San Antonio. (See the Handbook of Operating Procedures (**HOP**), Policy 3.2.5)
- 7. A **Statement of Purpose (a.k.a. Personal Statement)** (1-2 pages) that includes a brief description of the applicant's background, long term research and/or career goals, and an indication of the basis for application into the MSCI-TS Program including how this program fits into the applicant's career objectives. The Statement of Purpose should be submitted with the online application to the GSBS.
- 8. Current curriculum vitae. This should be submitted with the online application to the GSBS.
- 9. A copy of current visa (Foreign National Applicants).
- 10. Copy of U.S. Medical License/Certificate for licensed health care professionals.

Official test scores, transcripts, and foreign transcript translations, mentioned above, should be sent to:

Registrar's Office-Graduate Admissions - MSC 7702 UT Health San Antonio7703 Floyd Curl Drive San Antonio, Texas 78229-3900

Applicants should utilize the <u>Applicant Checklist</u> of required documentation for admission that is provided on the <u>MSCI-TS Forms</u> webpage, an example can be found in the Appendix of this Handbook.

All of the **required** information described above **must** be submitted in order for an applicant to be considered by the MSCI-TS Student Admissions Committee. Requests for an exemption to any of these general admission requirements should be addressed to the MSCI-TS Program Director and sent directly to the MSCI-TS Academic Coordinator Via email (<u>Machuca@uthscsa.edu</u>).

Application Process

Application: An online application for admission into the MSCI-TS Program must be processed through UT Health San Antonio Graduate School of Biomedical Sciences (GSBS). This application is available at: <u>uthscsa.edu/academics/biomedical-sciences/what-know-you-apply.</u>

As described in the online application for admission into the GSBS, official transcripts from **ALL** colleges and universities attended by the applicant are required. Additionally, all transcripts from foreign institutions **must be translated and submitted by the ECE or WES agencies**. Official GRE and TOEFL or IELTS (academic version) test scores must also be submitted. For health care professionals, a copy of the applicant's medical license or other professional accreditation must also be submitted.

Deadlines: The MSCI-TS Program has an open application policy and will accept applications year round for admission as allowed by the EMBARK online application system. However, *GSBS deadlines* for admission 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 the Fall semester of each academic year.

Application Deadlines		
Fall Semester	April 1	
Spring Semester	October 1	
Applicants Requiring an F-1, J-1 or H-1B Visa:		
Fall Semester Only:	February 1	

Applicants will have the responsibility for the timely submission of application materials to the MSCI-TS 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-TS Admissions Committee will review and provide a recommendation to the Dean of the Graduate School for Biomedical Sciences for final approval.

The MSCI-TS 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, if applicable, TOEFL or IELTS (academic version) tests, research experience, and all other required documentation submitted with the online application or sent directly to the MSCI-TS Academic Programs Coordinator. Research experience is not required but may be beneficial.

After sequential review by the MSCI-TS Admissions Committee, and the GSBS, applicants will be formally notified of the outcome by the Dean of the UT Health San Antonio's Graduate School for Biomedical Sciences. The MSCI-TS Admissions Committee recommends admission to the most highly qualified applicants regardless of ethnicity, gender, age, sexual orientation, nation of origin, or disability.

Tuition and Fees

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

The UT Health San Antonio "<u>Excess Credit Hours Policy</u>" can be found in the UT Health San Antonio Catalog at: <u>http://catalog.uthscsa.edu/generalinformation/excesscredithourspolicy/</u>. Under this policy a student who is enrolled in hours beyond the applicable credit hour limit will be charged out-of-state tuition.

Student Pathways through the MSCI-TS Program

After acceptance, students may complete the requirements for graduation while enrolled as either a full-time or part-time student. However, students on a F-1 visa are required to be enrolled as full-time students while completing the requirements for graduation.

Full-Time students: Full-time work is regarded as enrollment in at least eight (8) semester credit hours (SCH) during the Fall and Spring semesters. However, to complete the MSCI-TS Program in two years (with approval of an approved research project at entry) the student must enroll for at least nine (9) SCH. For students with an approved research project, this is usually six (6) SCH of didactic seminars/lectures and three (3) SCH of research credit. *Thus, to enroll as a full-time student upon admission, students must have an approved Supervising Professor, Research Supervising Committee (RSC), and research project at the time of application into the program.* If the Supervising Professor, RSC, and research project are established and approved by the MSCI-TS COGS at the time of admission, and enrolls in at least nine (9) SCH the full-time student can expect to complete the course requirements for an MSCI-TS within 2 years.

For applicants who anticipate completion of the requirements for graduation within 2 years, it is highly recommended that the Supervising Professor, Research Supervising Committee, be identified and a Research Project Proposal documentation packet be submitted for review at the time of the initial application into the program.

Part-time Students: Part-time students are enrolled for **less than** eight (8) SCH credit hours per semester during the Fall or Spring semesters. Earning the MSCI-TS degree as a part-time student will usually require three (3) to four (4) years. A part-time student must enroll in **at least** four (4) SCH per semester.

UT Health San Antonio Faculty and Staff as Students in the MSCI-TS Program: UT Health San Antonio faculty and staff may apply for admission in the MSCI-TS Program. However, faculty must adhere to the <u>HOP Policy 3.2.5</u>. "Work Towards Advanced Degree". 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 San Antonio <u>Catalog</u> and <u>Handbook of Operating Procedures</u> (HOP).

Foreign Nationals Applicants/Students in the MSCI-TS Program: Consistent with the aims of the MSCI-TS Program, the MSCI-TS 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 UT Health San Antonio. As a consequence, denying access to the MSCI-TS courses to foreign national applicants/students potentially puts them at a disadvantage in their research education and experiences. Additionally, the MSCI-TS Program will directly benefit from the J-1 and H-1B visa programs because the skills taught in the MSCI-TS courses will enhance the quality of the candidates' work that they were hired to do under the auspices of these visas. Any individual on a J-1 Research Scholar visa will be referred to the Office of International Services for review and approval.

Accordingly, the MSCI-TS 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-TS degree, but enrollment in classes must be incidental to their primary activities for which they came to UT Health San Antonio.
- 2. They may enroll as part-time students in up to four (4) SCH of didactic course work per semester; enrollment in more than four (4) SCH requires prior approval from the <u>Office of International Services</u>.
- 3. They may enroll in research semester credit hours under the supervision of their Supervising Professor. The research semester credit hours are directly relevant to and obtained from the work these individuals are conducting at UT Health San Antonio while on their J-1 or H-1B visa. The number of research semester credit hours allowed per semester will be determined on a case-by-case basis contingent upon the individual circumstances of the student.
- 4. At no time, will participation in the MSCI-TS 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 San Antonio.

Foreign nationals who seek admission to the MSCI-TS Program as full-time students are required to obtain an F-1 visa.

An approved Supervising Professor is required for the successful completion of the MSCI-TS Program; however, it is **not** a prerequisite in consideration for admission into the program **<u>unless</u> <u>entering the MSCI-TS Program on a F-1, J-1 or H-1B visa status.</u>**

Non-Degree Seeking Students in the GSBS: Individuals wishing to enroll in MSCI-TS courses without admission into the MSCI-TS Program can do so either as a student from a different GSBS graduate degree program or as a non-degree seeking student who has applied and been accepted into the <u>GSBS Non-degree Seeking Student Program</u>. (Note: GSBS non-degree seeking students are *independent* of the MSCI-TS Program.) Individuals who have matriculated in other UT Health San Antonio schools (*e.g.*, Medical School, Dental School, Nursing School, or the School of Health Professions) as well as faculty, staff, or other employees will be required to complete a <u>GSBS online application</u> for acceptance into the GSBS Non-degree Seeking Student Program. The appropriate MSCI-TS Course Director must approve the enrollment of any GSBS non-degree seeking student in

their course by signing the GSBS non-degree seeking student's course card (provided by the GSBS Dean's office).

Course credit earned as a GSBS non-degree seeking student can be applied towards an MSCI-TS degree following formal application and acceptance into the MSCI-TS Program. A Master Degree in Clinical Investigation and Translational Science cannot be obtained as a GSBS non-degree seeking student. If an applicant has completed all required MSCI-TS courses as a non-degree seeking student in the GSBS, they must be eligible to enroll in the MSCI-TS course, Mentored Research in Clinical Investigation (TSCI 6097), at the time of application to the MSCI-TS program. Therefore, they must have identified a Supervising Professor, Research Supervising Committee, and submitted their Research Project Proposal documentation packet as part of their application.

Degree Requirements

Successful completion of the MSCI-TS Program requires the satisfactory completion of all required coursework, completion of a MSCI-TS COGS approved Research Project Proposal, submission of a manuscript to a peer-reviewed publication, and the MSCI-TS COGS' approval of the student's manuscript.

Students who are accepted into the MSCI-TS Program are required to establish a Supervising Professor at either the time of application (encouraged) or within one year of admission to the program. Additionally, the student must establish their Research Supervising Committee after the establishment of their Supervising professor. It is the responsibility of the student to seek out a MSCI-TS Graduate Faculty member and establish their commitment to serving as their Supervising Professor.

Coursework: Thirty (30) semester credit hours (SCH) are required to obtain the MSCI-TS degree. Students must satisfactorily complete all *required courses*. Students must complete:

- 18 (SCH) of required courses
- 12 (SCH) of elective courses.

Research Project Proposal: One of the main requirements of the MSCI-TS degree is to have students produce a Research Project Proposal (RPP) under the direction of their Supervising Professor (SP) and their Research Supervising Committee (RSC).

Manuscript: Upon satisfactory completion of all required courses, students must submit a manuscript to a peer-reviewed journal and have the MSCI-TS COGS review and approve the manuscript for eligibility of candidacy for the MSCI-TS degree.

Supervising Professor

Supervising Professor: The Supervising Professor will oversee all aspects of the student research project and must be a member of the MSCI-TS Graduate Faculty. The Supervising Professor will act as a guide to help the student through the process of establishing a Research Supervising Committee, Research Project Proposal, and the collection of data, analysis and writing of their Research Project Proposal and later their manuscript.

In the event that a student identifies a Supervising Professor who is not a member of the MSCI-TS Graduate Faculty, the MSCI-TS COGS will separately assess the qualifications of that individual for recommendation to the GSBS for appointment to the MSCI-TS Graduate Faculty. Requests for consideration of appointment to the MSCI-TS Graduate Faculty may be considered concurrently with the evaluation of an individual to serve as a student's Supervising Professor.

Details and requirements for MSCI-TS Graduate Faculty appointment are provided in the MSCI-TS (Programmatic) Graduate Faculty section of the MSCI-TS Handbook. No Supervising Professor may have more than five (5) MSCI-TS students at a given point in time; exception to this limit requires special consideration by the MSCI-TS COGS.

The proposed Supervising Professor must submit a letter of commitment to be included in the student's Research Project Proposal documentation packet forwarded to the MSCI-TS COGS through the MSCI-TS Academic Programs Coordinator. The letter of commitment must include the following:

- Brief overview of the planned research project that has been reviewed and approved by the student's Research Supervising Committee.
- Explicit 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-TS Program
- If the student is a foreign national on a J-1, H-1B, or F-1 visa, the Supervising Professor must submit a letter with a statement of commitment to the student's education and training biannually prior to the beginning of each semester.

The Supervising Professor must be established within one year of enrollment into the MSCI-TS program along with the Research Supervising Committee, Research Project Proposal and Student/Supervising Professor Compact. Exceptions must be approved by the MSCI-TS COGS and will be evaluated on a case-by-case basis after submission of a written request to the MSCI-TS Program Director through the MSCI-TS Academic Programs Coordinator.

Research Supervising Committee

Research Supervising Committee: The student, with the help of his/her Supervising Professor, will select a Research Supervising Committee (RSC). The RSC shall consist of the Supervising Professor (chair), a member of the MSCI-TS COGS, a member of the MSCI-TS Graduate Faculty; and an External Expertise Specific member to provide specific expertise in the planned area of study. The RSC must be comprised of four (4) separate members, including the external expertise specific member, as members of the student's Research Supervising Committee cannot serve in multiple roles within the Committee. The RSC will advise and guide the student on their Research Project Proposal and manuscript development.

The RSC must be established within one year of enrollment into the MSCI-TS program. Exceptions must be approved by the MSCI-TS COGS and will be evaluated on a case-by-case basis after submission of a written request to the MSCI-TS Program Director through the MSCI-TS Academic Programs Coordinator.

Research Project Proposal

Research Project Proposal: The first duty of the Research 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-TS COGS. It is anticipated that the project/written proposal will be the student's work. The written proposal should not exceed *six* double-spaced typewritten pages and should include the following sections:

- 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)
- Reference (not included in the 6 page limit)

Once the written research proposal has been approved by the RSC, the proposal shall be forwarded to the MSCI-TS Academic Coordinator/COGS for review and approval action. The research proposal must be accompanied by:

- 1. RSC List and Signature Approval of Research Project Form
- 2. Supervising Professor's letter of commitment
- 3. Supervising Professor's curriculum vita
- 4. External Expertise Specific Faculty's curriculum vitae
- 5. Research Project Proposal
- 6. Research Proposal Assessment Form
- 7. Student/Supervising Professor Compact.

After MSCI-TS COGS approval, the student will then begin participating in mentored research activities under the direction of the Supervising Professor and register to receive research course credit (TSCI 6097 – Mentored Research in Clinical Investigation). The Research Course is set up for the student to conduct their Mentored Research Project with their Supervising Professor. 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 a manuscript.

Change in Supervising Professor, Research Supervising Committee or Research Project Proposal

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

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

1. Cover memo that describes the basis for the request to change the Supervising Professor

- 2. A letter of commitment from the proposed Supervising Professor (with details as described above for the initial Supervising Professor's letter of commitment)
- 3. Curriculum Vita of the proposed Supervising Professor
- 4. <u>Compact Between MSCI-TS Student and Supervising Professor</u> form (see Appendix)
- 5. <u>Request to Amend MSCI-TS Student Research Program</u> form (see Appendix)

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

- 1. Cover memo that describes the basis for the request to change the Research Supervising Committee membership
- 2. <u>Request to Amend MSCI-TS Student Research 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 RSC prior to review and approval action by the MSCI-TS COGS. The written request to change the research project must be submitted to the MSCI-TS Program Director through the MSCI-TS 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-TS Student Research Program</u> form (see Appendix)

Manuscript Requirement

A basic tenet of the MSCI-TS Program is the expectation that MSCI-TS 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 Research Supervising Committee (RSC), each student is required to submit a manuscript to the MSCI-TS COGS for review and approval towards their eligibility for candidacy for the MSCI-TS 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-TS 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-TS degree.
- Students are not required to be the first author on the manuscript, but must be a primary author. It is the general consensus of the MSCI-TS COGS that the primary author is demonstrated as the 1st or 2nd author on a peer-reviewed publication. 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 was approved by the MSCI-TS COGS. In the event that either of these is not the case, a detailed written explanation must be provided by the Supervising Professor.

- The manuscript should be provided to the Research Supervising Committee for review and approval <u>at least 2 weeks</u> prior to submission to the MSCI-TS COGS. When submitted to the RSC:
 - It is required that the manuscript be evaluated by the Research Supervising Committee **prior** to submission for publication.
- 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.
- After approval by the Research Supervising Committee, the <u>Manuscript Approval Form</u> should be completed and signed/dated by all members of the Research Supervising Committee.
- The manuscript can be submitted to the MSCI-TS COGS at any time, however, in cases with impending graduation deadlines, the approved manuscript should be provided to the MSCI-TS COGS <u>at least one month prior</u> to the regularly-scheduled graduation date established by the Graduate School of Biomedical Sciences (GSBS).
- When the manuscript is submitted to the MSCI-TS COGS, it should be accompanied by:
 - 1. <u>Manuscript Approval Form</u>
 - 2. Supervising Professor's Letter (described above)
 - 3. Journal Submission Date: A dated notice (letter or e-mail) from the publisher that indicates manuscript submission/acceptance
 - 4. Student's Manuscript
 - 5. <u>Manuscript Assessment Form</u> (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-TS manuscript requirement applies to all students who seek to complete the MSCI-TS Program.

Coursework & Grading

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

Required Courses: Degree-seeking students in MSCI-TS Program must successfully complete the following 18 SCH of didactic courses.

TSCI 5070 (2 SCH)	Responsible Conduct of Research
TSCI 5071 (2 SCH)	Patient-Oriented Clinical Research Methods -I
TSCI 5072 (2 SCH)	Patient-Oriented Clinical Research Biostatistics - I
TSCI 5073 (1 SCH)	Integrating Molecular Biology with Patient-Oriented Clinical Research
TSCI 5074 (2 SCH)	Data Management, Quality Control, and Regulatory Issues

TSCI 5075 (2 SCH)	Scientific Communication
TSCI 5080 (1 SCH)	Integrating Molecular Biology with Patient-Oriented Clinical Research Practicum (Prerequisite: TSCI 5073)
TSCI 6060 (2 SCH)	Patient-Oriented Clinical Research Methods -2 (Prerequisite: TSCI 5071)
TSCI 6061 (2 SCH)	Patient-Oriented Clinical Research Biostatistics – 2 (Prerequisite: TSCI 5072)
TSCI 6065 (2 SCH)	Health Services Research (Prerequisite: TSCI 5071 & TSCI 6060)

Research Course: In a given semester, MSCI-TS students with an approved Research Project **Proposal**, may enroll to receive course credit (1.0 - 4.5 SCH) for research, *i.e.*, after MSCI-TS COGS approval of the Supervising Professor, Research Supervising Committee (RSC), and research project.

	Mentored Research in Clinical Investigation
TSCI 6097 (1-4.5 SCH)	(Prerequisite: MSCI-TS COGS approval of a Supervising Professor, Supervising Committee, and a research project)

MSCI-TS students must enroll in TSCI 6097 Mentored Research for at least two semesters to be eligible for consideration for graduation. Although it is possible to enroll for more than 3 semester credit hours of research credit in any given semester, approval of greater than 3.0 (16 weeks of research) or 4.5 (24 weeks of research) semester credit hours requires written approval by the MSCI-TS Program Director and will be considered on a case-by-case basis. A written request for permission to enroll in more than 3.0 - 4.5 SCH must be submitted to the MSCI-TS Program Director through the MSCI-TS Academic Coordinator (in advance of registration) and should include a brief description of the basis of the request and total hours per week the student works on his research project.

Thesis Course: MSCI-TS Students wishing to graduate are required to enroll in 1.0 semester credit hour (SCH) of TSCI 6098 Thesis for at least one semester, not to exceed two semesters. It is required that MSCI-TS graduating students will enroll in TSCI 6098 Thesis during the semester they will be submitting their manuscript to the MSCI-TS COGS for approval.

	Thesis
TSCI 6098 (1 SCH)	(Prerequisite: MSCI-TS COGS approval of a Supervising Professor,
	Supervising Committee, and a research project proposal)

Elective Courses: 12 SCH of diverse elective courses are sponsored by the MSCI-TS Program and are available and may be taken in any semester when offered. These include:

TSCI 5050 (1.0 SCH)	Introduction to Data Science
TSCI 5076 (1 SCH)	Introduction to Informatics

TSCI 5077 (1 SCH)	Translational Science Practicum (Prerequisite: Consent of the Course Director)
TSCI 5078 (1 SCH)	Introduction to Intellectual Property, Technology Transfer, and Commercialization
TSCI 5079 (1 SCH)	Practicum in Intellectual Property, Technology Transfer, and Commercialization
TSCI 6001 (1 SCH)	Introduction to Translational Science
TSCI 6064 (1 SCH)	Grantsmanship and Peer Review
TSCI 6066 (1 SCH)	Instrument Development and Validation
TSCI 6067 (1 SCH)	Genomic Healthcare
TSCI 6068 (1 SCH)	Cross Cultural Adaptation of Research Instruments
TSCI 6069 (2 SCH)	Statistical Issues, Planning, and Analysis of Contemporary Clinical Trials (Prerequisite: TSCI 5072 & TSCI 6061)
TSCI 6070 (2.5 SCH)	Biostatistics Methods for Longitudinal Studies (Prerequisite: TSCI 5072 & TSCI 6061)
TSCI 6100 (1 SCH)	Practicum in IACUC Procedures
TSCI 6101 (1 SCH)	Topics in Translational Science
TSCI 6102 (1 SCH)	Practicum in IRB Procedures
TSCI 6103 (1 SCH)	Selected Topics in Advanced Research Ethics
TSCI 6105 (1 SCH)	Topics in Cancer Prevention
TSCI 6106 (0.5 – 1 SCH)	Practicum in Cancer Prevention Science

In addition to the elective courses outlined above, requests for substitution of other graduate level courses will be considered on a case-by-case basis. A written request for consideration of alternative elective coursework must be submitted to the MSCI-TS Program Director through the MSCI-TS Academic Coordinator.

Timeline for Coursework: A typical schedule for a full-time MSCI-TS student is provided in the Appendix together with descriptions of MSCI-TS Program-sponsored courses.

Grade Requirement: Student performance in MSCI-TS-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-TS 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-TS COGS will provide a recommendation as to whether or not the student is to be dismissed from the MSCI-TS Program.

Exemption of Required Course: Exemption of the requirement for completion of a required course will be considered by the MSCI-TS COGS on a case-by-case basis. A written request for exemption of a required course must be submitted to the MSCI-TS Program Director through the MSCI-TS Academic Coordinator and should include a brief description of the reason(s) for the request as well as documentation (publication copies, meeting abstracts, etc.) supporting the reason(s) for the request.

Transfer of Coursework for Credit: In the event that a student has successfully completed graduate level coursework that is duplicative of required or elective MSCI-TS 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-TS course must include the following documentation and be submitted to the MSCI-TS Program Director through the MSCI-TS Academic Coordinator.

- 1. A written request that includes a comprehensive description of the prior course detailing when and where completed, course semester credit hours, and details of course content and objectives.
- 2. An official copy of the student's transcript that indicates successful course completion and the grade issued.
- 3. A copy of the course description from the catalog that was in effect during the semester the course was taken.
- 4. A course syllabus is suggested but not required.

MSCI-TS COGS approval of a request for course exemption does not grant the student credit for the semester credit hours associated with the course. The semester credit hours for the exempted course can be obtained by taking a MSCI-TS elective course or additional mentored research hours. Transfer of coursework for credit is described below.

If the transfer of credit request is approved by the MSCI-TS COGS, the MSCI-TS Academic Coordinator will prepare a request for transfer of course credit and submit it 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-TS course. As per GSBS rules, no more than 6 semester credit hours may be transferred towards the completion of a Master's of Science degree.

Coursework during the Semester of Graduation: Other than TSCI 6097 Mentored Research or TSCI 6098 Thesis, students **cannot** be enrolled in coursework towards the 30 semester credit hour requirement during the semester of graduation. Requests to enroll in coursework towards Students **must** be enrolled in the GSBS during the semester of graduation.

Class Attendance and Makeup Policy

Attendance: The UT Health San Antonio MSCI-TS 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 of the class and until 15 minutes before the scheduled ending of the class.

Excused absences may be granted by the Course Director 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 e-mail 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). 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-TS Program Requirements



Laptop Computer Requirement: The MSCI-TS Program requires each student to have a laptop computer that can connect to and operate over a wireless network. Software required:

- Microsoft Office Suite (A personal copy of the latest version can be purchased at UT Health San Antonio bookstore at student pricing with a student ID)
- R & R Studio (Open source, free, latest version) <u>https://www.rstudio.com/products/RStudio/</u> <u>https://www.r-project.org/</u>

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

All laptops will connect to UT Health San Antonio network via the HSCwave broadcast wireless connection. Authentication for wireless use is based on The UTHSCSA domain username and password. Verification of proper operation **prior** to the start of class is highly recommended.

Assistance is available thru the IMS Service Desk (210-567-7777 or <u>ims-servicedesk@uthscsa.edu</u>). Assistance is also available at the IMS Student Support Center (ALTC 106).

Semi-Annual Student Evaluation

<u>Students with an approved research project</u> will be evaluated by the Supervising Professor and Research Supervising Committee (RSC) at least once every six months throughout the remainder of their enrollment in the MSCI-TS Program. The Student/Supervising Professor Compact will be reviewed by the student and supervising professor and submitted with the fall semester Semi-Annual Student Evaluation due by August 31st. Following MSCI-TS COGS approval of the research project and Student/Supervising Professor Compact, the semi-annual student evaluation and the reviewed Student/Supervising Professor Compact must be submitted to the MSCI-TS COGS by **August 31**st and February 28th of each year irrespective of the date of the MSCI-TS COGS approval of the research project. Once a student has completed all requirements for completion of the MSCI-TS Program, no further semi-annual evaluations or reviewed Student/Supervising Professor Compacts will be required.

Requests for extension of the deadline for submission of all documents associated with the semiannual evaluation (see below) and Student/Supervising Professor Compact will be considered on a caseby-case basis. A written request for extension should be directed to the MSCI-TS Program Director through the MSCI-TS 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 (*TSCI 6097 Mentored Research*) in the corresponding semester (Fall semester for the August 31st deadline and Spring semester for the February 28th deadline). 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. If a student receives a grade of "Unsatisfactory" (U) the semester credit hours (SCH) will not be counted towards the total 30 SCH required for graduation.

To accomplish this evaluation, the student shall submit to the RSC 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 <u>MSCI-TS Semi-Annual Student Evaluation</u> form (by the student and Supervising Professor) and a formal meeting of the student's RSC. The Supervising Professor shall serve as the Chair of the student's Research Supervising Committee and is expected to establish the time and place of the meeting. The student shall be present during this formal meeting of the RSC and is expected to provide a brief overview of his/her research and training activities, any problems encountered since the previous meeting with the RSC, as well as plans for the future towards completion of the requirements in

fulfillment of the MSCI-TS Program. If requested, the student may be asked to leave the meeting during Supervising Committee's deliberations.

The RSC 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-TS course work, research, seminars and other MSCI-TS Program activities.

If progress is unsatisfactory, the RSC shall discuss the reasons for this decision with the student. Then, the Supervising Professor and student shall develop a plan for remediation which is to be submitted with the semi-annual evaluation. In this case, the student will be required to, following the semi-annual evaluation process, submit an updated <u>MSCI-TS Student Semi-Annual Student Evaluation</u> within three months of the original unsatisfactory semi-annual evaluation.

The Supervising Professor will follow up each RSC/student meeting with a memorandum to every member of the RSC specifying the Research 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-TS Program Director through the MSCI-TS Academic Programs Coordinator together with the <u>MSCI-TS Semi-Annual MSCI-TS Student Evaluation</u> form that includes the Student Progress Report form (see Appendix) for processing and further review by the MSCI-TS Student Advisory Subcommittee prior to presentation to the MSCI-TS COGS.

Failure of a student to show satisfactory progress toward his/her degree goal may be grounds for dismissal from the Program. The MSCI-TS 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) by the Program Director. The Dean of the GSBS will be notified of any student who receives unsatisfactory evaluations in two consecutive periods.

Ethics/Professionalism Policy

The MSCI-TS 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 San Antonio <u>Catalog</u> and <u>Handbook of Operating Procedures</u>. 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.

MSCI-TS (Programmatic) Graduate Faculty

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

- Curriculum Vita (PDF)
- <u>MSCI-TS Graduate Faculty Trainee Table</u> (Form), a copy of a recent NIH grant trainee table will be accepted in lieu of the MSCI-TS Graduate Faculty Trainee Table.

In consideration of individuals for membership in the MSCI-TS 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-TS Graduate Faculty will be automatically reviewed at least once every three (3) years. Requests for appointment to the MSCI-TS 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-TS Graduate Faculty is included in the Appendix

Completion of the MSCI-TS Program

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

Time-to-Master's Degree: It is expected that that the MSCI-TS 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-TS student who enrolled full-time has not graduated in 3 years (or a part-time student has not graduated in 4 years), the MSCI-TS COGS Chair will form a special committee independent of the Student's Research 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.

Helpful Online Connections

MSCI-TS Program	http://iims.uthscsa.edu/ed_msci_overview.html
MSCI-TS Forms	http://iims.uthscsa.edu/ed_msci_forms.html
MSCI-TS Course Schedules	http://iims.uthscsa.edu/sites/iims/files/Education/MSCI/Co urse-Schedule.pdf
<u>Graduate School of Biomedical Sciences</u> (GSBS)	http://gsbs.uthscsa.edu/
GSBS Application for Admission	https://www.uthscsa.edu/academics/biomedical- sciences/what-know-you-apply
GSBS Academic Calendar	http://students.uthscsa.edu/registrar/wp- content/uploads/sites/2/2013/04/School-of-GSBS.pdf
<u>GSBS Syllabus Depot</u>	http://gsbssyllabus.uthscsa.edu/
Office of Student Services (Registrar)	http://students.uthscsa.edu
Office of International Services	http://www.uthscsa.edu/ois
<u>CANVAS</u>	http://www.uthscsa.edu/university/canvas
<u>UT Health Catalog</u>	http://catalog.uthscsa.edu/
<u>UT Health 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/

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2019-2020 Committee on Graduate Studies (MSCI-TS COGS)

Donald M. Dougherty, PhD MSCI-TS COGS Chairman

Goutam Ghosh-Choudhury, PhD Medicine/Renal Diseases

Helen P. Hazuda, PhD Medicine/Renal Diseases

Teresa Johnson-Pais, PhD Urology

Donna M. Lehman, PhD Medicine/Cardiology

Philip T. LoVerde, PhD Biochemistry/Pathology

Linda M. McManus, PhD Pathology

Polly H. Noel, PhD Family & Community Medicine

Hai Rao, PhD Molecular Medicine

Bill Sanns, BA Epidemiology & Biostatistics

Joseph O. Schmelz, PhD Office of the VP for Research Maureen J. Simmonds, PhD, PT Physical Therapy

Kimberly Summers, PharmD Research Regulatory Program

Rudy J. Trevino, MS, CPIA Research Regulatory Program

Chen-Pin Wang, PhD Epidemiology and Biostatistics

Michael J. Wargovich, PhD Molecular Medicine/CTRC

Meyad Baghezza, BA, CIP Research Regulatory Program

Alex Bokov, PhD Epidemiology & Biostatistics

Carrie Jo Braden, RN, PhD Nursing

Leonid Bunegin, BSc Anesthesiology

Andrew Cap, MD, PhD, FACP Program Director Clinical Investigation Fellowship San Antonio Military Medical Center

Byeongyeob Choi, PhD Epidemiology & Biostatistics

Robert A. Clark, MD Office of the VP for Research

Donald M. Dougherty, PhD Psychiatry/Alcohol & Drug Abuse

Bertha E. Flores, PhD, APRN School of Nursing

Christopher Frei, PharmD, MSc Pharmacology Ed& Research Cntr

Jonathan Gelfond, MD, PhD Epidemiology and Biostatistics

2019-2020 <u>MSCI</u>-TS Graduate Faculty

Seema Ahuja, MD Medicine/Renal Diseases

Sunil K. Ahuja, MD Medicine/Infectious Disease

Bennett T. Amaechi, BDS, PhD Comprehensive Dentistry

Antonio R. Anzueto, MD Medicine/Pulmonary Disease

Cynthia Blanco, MD Pediatrics/Neonatology

Alex Bokov, PhD Epidemiology & Biostatistics

Charles L. Bowden, MD Psychiatry

Carrie Jo Braden, RN, PhD School of Nursing, Dean's Office

Andrew Brenner, MD, PhD Medicine

Leonid Bunegin, BSc Anesthesiology

Andrew Cap, MD, PhD, FACP Program Director Clinical Investigation Fellowship San Antonio Military Medical Center

Eugenio Cersosimo, MD Medicine/Diabetes

Bandana Chatterjee, PhD Molecular Medicine

Byeongyeob Choi, PhD Epidemiology & Biostatistics

Robert A. Clark, MD Office of the VP for Research

David L. Cochran, DDS, PhD Periodontics Jannine D. Cody, PhD Pediatrics/Cytogenetics

Ralph A. DeFronzo, MD Medicine/Diabetes

Immaculada del Rincon, MD Medicine/Clinical Immunology

Donald M. Dougherty, PhD Psychiatry/Alcohol & Drug Abuse

Agustin Escalante, MD Medicine/Clinical Immunology

Gabriel Fernandes, PhD Medicine/Clinical Immunology & Rheumatology

Robert L. Ferrer, MD Family & Community Medicine

Kristin R. Fiebelkorn, MD Pathology

Bertha E. Flores, PhD, APRN School of Nursing

Christopher Frei, PharmD, MSc Pharmacology Ed& Research Cntr

Jonathan Gelfond, MD, PhD Epidemiology and Biostatistics

Goutam Ghosh-Choudhury, PhD Medicine/Renal Diseases

Alice K. Gong, MD Pediatrics

Kenneth Hargreaves, DDS, PhD Endodontics

Helen P. Hazuda, PhD Medicine/Renal Diseases

Martin Javors, PhD Psychiatry Scott B. Johnson, MD Cardiothoracic Surgery

Teresa Johnson-Pais, PhD Urology

Balakuntalam S. Kasinath, MD Medicine/ Renal Diseases

David Katerndahl, MD Family & Community Medicine

Nancy D. Kellogg, MD Pediatrics/Child Abuse

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

George B. Kudolo, PhD Clinical Laboratory Sciences

Jack L. Lancaster, PhD Research Imaging Institute

Robin J. Leach, PhD Cellular and Structural Biology

Donna M. Lehman, PhD Medicine/Cardiology

Senlin Li, MD Medicine/Infectious Disease

Philip T. LoVerde, PhD Biochemistry/Pathology

Donald C. McCurnin, MD Pediatrics/Neonatology

Linda M. McManus, PhD Pathology

Joel E. Michalek, PhD Epidemiology & Biostatistics

Shamimunisa B. Mustafa, PhD Pediatrics/Neonatology Polly H. Noel, PhD Family & Community Medicine

Michael Odom, MD Pediatrics/Neonatology

Alexis Ortiz, PT, PhD Physical Therapy

Babatunde O. Oyajobi, PhD Cellular & Structural Biology

Raymond F. Palmer, PhD Family & Community Medicine

Robert W. Parker, MD Family & Community Medicine

Thomas F. Patterson, MD Medicine/Infectious Diseases

Jay I. Peters, MD Medicine/Pulmonary Diseases

Thomas Prihoda, PhD Pathology

Mary Jo Pugh, MD Epidemiology & Biostatistics

Rajam S. Ramamurthy, MD Pediatrics

Patrick S. Ramsey, MD, MSPH OB-GYN

Yolanda M. Rangel, PhD Physical Therapy

Hai Rao, PhD Molecular Medicine

Marcos Restrepo, MD Medicine/Pulmonary Disease

John D. Rugh, PhD Developmental Dentistry

Bill Sanns, BA Epidemiology & Biostatistics

Joseph O. Schmelz, PhD Office of the VP for Research

Susanne Schmidt, PhD Epidemiology & Biostatistics Martin G. Schwacha, PhD Surgery

Wayne H. Schwesinger, MD Surgery

Steven R. Seidner, MD Pediatrics/Neonatology

Paula K. Shireman, MD Surgery/Vascular Surgery

Maureen J. Simmonds, PhD, PT Physical Therapy

Ronald M. Stewart, MD Surgery

Kimberly Summers, PharmD IRB/Research Protection Programs

Rajeshwar R. Tekmal, PhD Obstetrics and Gynecology

Gail Tomlinson, MD, PhD Pediatrics/Hematology-Oncology

Devjit Tripathy, MD Medicine/Diabetes

Ratna K. Vadlamudi, PhD Obstetrics & Gynecology

Manjeri A. Venkatachalam, MBBS Pathology

Chen-Pin Wang, PhD Epidemiology and Biostatistics

Michael J. Wargovich, PhD Molecular Medicine/CTRC

Nathan P. Wiederhold, PharmD Pathology/Laboratory Medicine

Steven D. Weitman, MD, PhD Pediatrics

Ross Wills, PhD Surgery

Typical schedule for a full-time MSCI-TS Student

Year 1 – Fall Semester

TSCI 5070 (2 SCH) – Responsible Conduct of Research TSCI 5071 (2 SCH) – Patient Oriented Clinical Research Methods -1 TSCI 5072 (2 SCH) – Patient Oriented Clinical Research Biostatistics -1 TSCI 5075 (2 SCH) – Scientific Communications

Year 1 – Spring Semester

TSCI 5073 (1 SCH) – Integrating Molecular Biology with Patient Oriented Clinical Research TSCI 5074 (2 SCH) – Data Management, Quality Control, and Regulatory Issues TSCI 6060 (2 SCH) – Patient Oriented Clinical Research Methods -2 TSCI 6061 (2 SCH) – Patient Oriented Clinical Research Biostatistics -2 TSCI 6097 (1 - 4.5 SCH) – Mentored Research in Clinical Investigation

Year 2 – Fall Semester

TSCI 5050 (1 SCH) – Introduction to Data Science (Elective) TSCI 5080 (1 hours) – Integrating Molecular Biology with Patient Oriented Clinical Research Practicum TSCI 6065 (2 hours) – Health Services Research TSCI 6070 (2.5 SCH) – Biostatistics Methods for Longitudinal Studies (Elective) TSCI 6097 (1 - 4.5 SCH) – Mentored Research in Clinical Investigation

Year 2 – Spring Semester* / graduation in May

TSCI 6098 (1 hours) – Thesis

*No formal classes should be required during this semester. The research project should be completed and a manuscript prepared and submitted. Students **must** complete **TSCI 6098** (**Thesis**) to be eligible for graduation and **must** be enrolled in the Graduate School in the semester of their graduation

Thirty (30) credit hours are required to obtain the MSCI-TS degree. Enrollment in *TSCI 6097 (Mentored Research in Clinical Investigation)* may occur in any semester after the Supervising Professor and Research Project Proposal have been submitted and approved by the MSCI-TS COGS.

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

TSCI 5050 (1 hour) – Introduction to Data Science
TSCI 5076 (1 hour) – Introduction to Informatics
TSCI 5077 (1 hour) – Practicum in Translational Science
TSCI 5078 (1 hour) – Introduction to Intellectual Property, Technology Transfer, and Commercialization
TSCI 5079 (1 hour) – Practicum in Intellectual Property, Technology Transfer, and Commercialization
TSCI 6001 (1 hour) – Introduction to Translational Science
TSCI 6064 (1 hour) – Grantsmanship and Peer Review
TSCI 6067 (1 hour) – Genomic Healthcare
TSCI 6069 (2 hour) – Statistical Issues, Planning, and Analysis of Contemporary Clinical Trials
TSCI 6070 (3 hour) – Biostatistics Methods for Longitudinal Studies
TSCI 6100 (1 hour) – Practicum in IACUC Procedures
TSCI 6101 (1 hour) – Topics in Translational Science
TSCI 6102 (1 hour) – Practicum in IRB Procedures
TSCI 6105 (1 hour) – Topics in Cancer Prevention
TSCI 6106 (1 hour) – Practicum in Cancer Prevention

Offerings Subject to Change without Notice

MSCI-TS Program	
2019-2020	
Tuition and Fee Breakdown	Estimate

Breakdown of Cost	Cost
Tuition - Texas Resident per semester credit hour (SCH)	50.00
Designated Deregulated Tuition per SCH	12.43
Tuition - Non-Texas Resident per SCH	472.00
Designated Deregulated Tuition per SCH	71.43
Differential Tuition per SCH	64.58
Designated Tuition per SCH	46.00
Fitness Center Fee	240.00
Student Service Fee	110.00
Medical Service Fee	106.20
Library Fee	150.00
Late Registration Fee	100.00
Graduation Fee (Semester Graduating)	100.00
Student Health Insurance	1,394.50

Tuition (per SCH):	1,500.00
Designated Deregulated Tuition (per SCH):	372.90
Differential Tuition (per SCH):	1,937.40
Designated Tuition (per SCH):	1,380.00
*Fitness Center Fee (Full-time = 4 semesters):	960.00
Student Service Fee (Full-time = 4 semesters):	440.00
*Medical Service Fee (Full-time = 4 semesters):	424.80
*Library Fee (Full-time = 4 semesters):	600.00
Graduation Fee (Graduating Semester):	100.00
Total (Based on Full-time Enrollment):	7,715.10
Non-Texas Resident (Total Does Not Include Student Insurance):	
Tuition (per sch):	14,160.00
Designated Deregulated Tuition (per sch):	2,142.90
Differential Tuition (per sch):	1,937.40
Designated Tuition (per sch):	1,380.00
*Fitness Center Fee (Full-time = 4 <u>semesters</u>):	960.00
*Student Service Fee(Full-time = 4 semesters):	440.00
*Medical Service Fee (Full-time = 4 <u>semesters</u>):	424.80
*Library Fee (Full-time = <u>4 semesters)</u> :	600.00
Diploma Fee (Graduating Semester):	100.00
Total (Based on Full-time Enrollment):	22,145.10

"<u>Click here for all MSCI-TS Forms</u>"

Master of Science in Clinical Investigation and Translational Science (MSCI-TS) Program APPLICATION CHECKLIST OF REQUIRED DOCUMENTATION
See MSCI-TS Handbook at <u>http://iims.uthscsa.edu/ed_msci_handbook.html</u> for full program requirements)
Submit an on-line application to The UT Health San Antonio Graduate School for Biomedical Sciences: https://www.uthscsa.edu/academics/biomedical-sciences/what-know-you-apply
Official transcripts of ALL colleges/universities attended sent from the institution to The UT Health San Antonio Registrar's Office as directed in the on-line application.
General Record Examination (GRE) scores (exam taken within the past five years) sent directly to The UT Health San Antonio from the Educational Testing Service (ETS). UTHSCSA code: 6908
Three Letters of Recommendation (LOR) should attest to the applicant's readiness for graduate level studies in clinical investigation and translational science and be addressed to Dr. Donald M. Dougherty, MSCI-TS Program Director.
UT Health San Antonio Faculty, Residents and Fellow Applicants <u>must include a LOR from their</u> <u>Department Chair</u> with statement indicating availability and approval of release of time for the completion of MSCI-TS educational and research activities.
UT Health San Antonio Staff Applicants <u>must include a LOR from their Authorized Supervisor</u> with statement indicating availability and approval of release of time for the completion of MSCI-TS educational and research activities.
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-TS Program.)
Curriculum vitae (CV) of applicant.
Copy of U.S. Medical License/Certificate
Foreign National Applicants applying with F-1, J-1 or H-1B Visas will also need to provide at time of application, the following documents:
Official translation of foreign transcripts including GPA of ALL foreign colleges/universities from the ECE or WES credentialing agencies should be sent from the credentialing agency to The UT Health San Antonio Registrar's Office. The translation <u>must be from the ECE or WES</u> credentialing agencies.
Test of English as a Foreign Language (TOEFL)or the academic version of the Test of English as a Foreign Language (IELTS) scores (test taken within the past two years) sent directly to The UTHSCSA from the ETS. UTHSCSA code: 6908
UT Health San Antonio Supervising Professor's Letter of Commitment/LOR (Includes a brief description of the applicant's research project/interest, and a statement of commitment to the applicant's career development. (<i>Note: If your Supervising Professor is not a member of the MSCI-TS Graduate Faculty please contact Alex Machuca at machuca@uthscsa.edu.</i>)
Supervising Professor's CV

Ma	ster of Science in Clinical Investigation & Translational Science (MS Student Program Status Checklist	SCI-TS) Prog	ram
	30 SCH are required for MSCI-TS Program Graduation.		
Required Co	oursework = 18 SCH / Elective Coursework = 12 SCH / TSCI 6097/6098 count toward	elective coursev	work
	REQUIRED COURSES: Course Number & Title	Semester	Pre-Req
YEAR 1: FAL	L Semester		
	TSCI 5070: Resp. Conduct of Research (2 SCH)	Fall	
	TSCI 5071: Patient Oriented Clinical Research Methods 1 (2 SCH)	Fall	
	TSCI 5072: Patient Oriented Clinical Research Biostatistics 1 (2 SCH)	Fall	
	Research Project Proposal (RPP) Submitted & Approved by MSCI-TS COGS		
YEAR 1: SPR	ING Semester		
	TSCI 5073: Integrating Molecular Biology w/ Patient Oriented Clinical Research (1 SCH)	Spring	
	TSCI 5074: Data Management, Quality Control & Regulatory Issues (2 SCH)	Spring	
	TSCI 6060: Patient Oriented Clinical Research Methods 2 (2 SCH)	Spring	TSCI 5071
	TSCI 6061: Patient Oriented Clinical Research Biostatistics 2 (2 SCH)	Spring	TSCI 5072
	TSCI 6097 Mentored Research in Clinical Investigation and Translational Science (1 – 4.5 SCH)	Fall & Spring	Approved RPP
YEAR 2: FAL	L Semester		
	TSCI 5075: Scientific Communication (2 SCH)	Fall	
	TSCI 5080: Practicum-Integrate Molecular Biology with Patient-Oriented Clinical Research (1 SCH)	Fall	TSCI 5073
		Fall	TSCI 5071
_		Fall	TSCI 6060
	ISCI 6097 Wentored Research in Clinical Investigation and Translational Science (1 – 4.5 SCH)		
YEAR 2: SPR	ING Semester		Approved
	TSCI 6098: Thesis (1 SCH)	Fall & Spring	RPP
	Manuscript Packet Submitted and Approved by MSCI-TS COGS (At least one month before graduation)		
	ELECTIVES: Course Number & Title	Semester	Pre-Req
	TSCI 5050: Introduction to Data Science (1 SCH)	Fall & Spring	
	TSCI 5076: Introduction to Informatics (1 SCH)	Spring	
	TSCI 5077: Practicum in Translational Science (1 – 3 SCH)	Fall & Spring	Course Director Approval
	TSCI 5078: Intro to Intellectual Property, Tech Transfer, & Commercialization (1 SCH)	Fall & Spring	
	TSCI 5079: Practicum in Intellectual Property, Tech Transfer, & Commercial (1 SCH)	Fall & Spring	
	TSCI 6001: Introduction to Translational Science (1 SCH)	Fall	
	TSCI 6064: Grantsmanship & Peer Review (1 SCH)	Spring	
	TSCI 6067: Genomic Healthcare (1 SCH)	Spring	
	TSCI 6069: Statistical Issues, Planning, & Analysis of Contemporary Clinical Trials (2 SCH)	Spring	
	TSCI 6070: Biostatistics Methods for Longitudinal Studies (2.5 SCH)	Fall	
	TSCI 6100: Practicum in IACUC Procedures (1 SCH)	Fall & Spring	
	TSCI 6101: Topics in Translational Science (1 SCH)	Fall & Spring	
	TSCI 6102: Practicum in IRB Procedures (1 SCH)	Fall & Spring	
	TSCI 6105: Topics in Cancer Prevention (1 SCH)	Fall	
	TSCI 6106:Practicum in Cancer Prevention (0.5 - 1 SCH)	Fall & Spring	

MSCI-TS Program RESEARCH PROPOSAL PACKET CHECKLIST
See MSCI-TS Handbook for detailed program requirements.
Submission Deadlines:
 Submit to Academic Coordinator for MSCI-TS COGS Monthly Meeting: February 1st (Applicants requesting or transferring a F-1 Visa) Last Friday of May (Fall Semester Enrollment in MEDI 6097-Mentored Research) 3rd Friday of November (Spring Semester Enrollment in MEDI 6097-Mentored Research)
Required Documentation:
The documentation below should be forwarded to the MSCI-TS Academic Coordinator via e-mail by the student, with the student's RSC members being copied, as separate PDF documents. Digital signatures are accepted.
Research Supervising Committee (RSC) List & Signature Approval of Research Project (Form)
All information, complete names, dates, and signatures are provided on the form.
Supervising Professor's Letter of Support Letter includes: Brief overview of the planned research project including the student's 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-TS Program If the student is a foreign national (F-1 or J-1 visa), an agreement to provide a bi-annual statement regarding continued support for enrollment in the MSCI-TS 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)
References (not included in the 6 page limit)
Supervising Professor's CV
External Expertise Specific Faculty Member's CV
Compact Between MSCI-TS Student & Supervising Professor (Form)
Research Proposal Assessment (Form)
Revised: 01/02/2018

MSCI-TS Program Research Supervising Committee (RSC) List & Signature Approval of Research Proposal (Form)	
Applicant/Student Name:	Date:
Research Proposal Title:	
Signatures below affirm that the applicant/stude approved at the required	ent's Research Plan has been reviewed and RSC group meeting.
Research Supervising Committee (RSC) Mem	bers:
Chair (Supervising Professor):	
Signature:	
Typed Name & Credentials:	
Department/Division:	
Institutional E-mail Address:	
MSCI-TS COGS Member:	
Signature:	
Typed Name & Credentials:	
Department/Division:	
Institutional E-mail Address:	
MSCI-TS Graduate Faculty Member:	
Signature:	
Typed Name & Credentials Name:	
Department/Division:	
Institutional E-mail Address:	
External Expertise Specific Faculty Member	
Signature:	
Typed Name & Credentials Name:	
Department/Division:	
Institutional E-mail Address:	
Student Signature:	
	Revised: 01/02/2018

Student Name:

Master of Science in Clinical Investigation and Translational Science (MSCI-TS) Program

Compact Between MSCI-TS Student and Supervising Professor

The MSCI-TS Program entails both formal education in advanced scientific knowledge and theory as well as research training under the supervision of an MSCI-TS Committee on Graduate Studies (COGS) approved Supervising Professor who is qualified to fulfill the responsibilities of a mentor. A positive mentoring relationship between the MSCI-TS student and the supervising professor is a vital component of the student's preparation for a successful biomedical career.

Individuals who pursue the MS in Clinical Investigation & Translational Science graduate degree are expected to take responsibility for their own scientific and professional development. Supervising Professors who advise MSCI-TS students are expected to fulfill the responsibilities of a mentor, including the provision of scientific training, guidance, and instruction in the responsible conduct of research and research ethics.

The Compact Between MSCI-TS Student and Supervising Professor (Compact)offers a set of <u>guiding principles</u> intended to promote and support the development of a positive mentoring relationship between the MSCI-TS student and his/her supervising professor.

MSCI-TS students will have discussed with their supervising professor each of the topics listed on pages 2-4 and submit the initial compact form as part of the MSCI-TS student's research proposal documentation packet to be approved by the MSCI-TS COGS. The initial Compact deadlines will be the same as the submission deadlines for the MSCI-TS student's research proposal documentation packet.

With their signatures and initials, both the supervising professor and the MSCI-TS student confirm that all topics listed have been discussed and they are committed to uphold the principles agreed upon in this individualized Compact. Once approved by the MSCI-TS COGS, the Compact will be placed in the MSCI-TS student's file held in the MSCI-TS Program's administration office.

It is understood that various aspects of the MSCI-TS student's pursuit of their degree can change over time; therefore, the Compact will be reviewed by the MSCI-TS student and supervising professor annually during the student's Fall semester semi-annual evaluation process and submitted for MSCI-TS COGS approval no later than August 31st.

Page 1 of 4

	Student Name:
	DEFINING MSCI-TS STUDENT AND SUPERVISING PROFESSOR RESPONSIBILITIES AND EXPECTATIONS
ſ	How often will the student and supervising professor meet in addition to the mandatory Research Supervising Committee (RSC) and student semi-annual evaluation meetings?
	How will updates or changes in expectations and issues be communicated?
	What is the policy related to the storage of data and/or records?
	What is the policy that constitutes authorship and how is the order of the authors determined on the student's manuscript and any other abstracts or journal publications?
	How many hours per week is the student expected to work on their research project and/or manuscript? Note: Enrolled in <u>3.0 sch of Mentored Research</u> : 144 hrs/semester – <u>9 hrs/16 weeks</u> Enrolled in <u>4.5 sch of Mentored Research</u> : 216 hrs/semester – <u>9 hrs/24 weeks</u>

a.	The student and supervising professor are each responsible for knowing and follow the guidelines/requirements in the MSCI-TS Handbook.
	Student Initials Supervising Professor Initials
b.	UT Health Certified or Adobe digital signatures are required on all MSCI-TS forms/documents.
	Student Initials Supervising Professor Initials
c.	Student's Research Supervising Committee (RSC) & Research Project Proposal Requirements:
	 The student is required to have a MSCI-TS COGS approved RSC consisting of the supervising professor (chair), a MSCI-TS COGS member, a MSCI-TS Graduate Faculty member, and an External Expertise Specific Faculty member. These for positions must be held by four separate individuals.
	Student Initials Supervising Professor Initials
	 The student with the help of the supervising professor will develop a research project proposal that meets the MSCI-TS requirements.
	Student Initials Supervising Professor Initials
	 The research project proposal that is developed must be completed and a manuscript submitted within the timeframe that the student is in the MSCI-TS Program (Full-time: 2 years, Part-time: 3 – 4 years).
	Student Initials Supervising Professor Initials
	 Any significant changes to the MSCI-TS COGS approved research project propo including but not limited to any change in the student's RSC or research plan w require submission of amended research documentation for MSCI-TS COGS approval.
	Student Initials Supervising Professor Initials
d.	MSCI-TS Student Semi-Annual Evaluations and Compact Reviews:
	 The Semi-Annual Student Evaluations are expected to be conducted in a timely fashion to ensure submission on or before the fall (August 31st) and the spring (February 28th) deadlines.
	Student Initials Supervising Professor Initials

and Res MSCI	Their Research earch Advisors -TS Compact Form (R	Advisors and the AAMC's Compact (December 2008). evised: 11/09/2017)	t Between Biomedical Graduate Students and	Their Page 4 of 4
C	Onflict re UTHSCS	esolution and stude A Student Catalog Geen adapted from the UT System P	nt complaint policies (refe (<u>http://catalog.uthscsa.e</u> c	r to the du/).
Su	pervising Pro	ofessor's Name, Credentials	Supervising Professor Signature	Date
4	Student	's Name, Credentials	Student Signature	Date
We add	have discu litions, spe	ssed all the above topics a cifications, and changes.	and made the mutually agreed upo	'n
7.	Additional	Topics		
	 After require COGS 	the manuscript has been sub red to submit a manuscript p 5 in order to be eligible for gr	mitted to a peer-reviewed journal, the acket for review and approval by the N aduation.	e student is 1SCI-TS
	81	Student Initials	Supervising Professor Initial	5
	• The s the R a pee	tudent's manuscript is requir SC prior to the mandatory st r-reviewed journal.	ed to be reviewed with the option for r udent/RSC manuscript meeting and su	evision by bmission to
	e. Student	Manuscript Requirements:		
	. <u> </u>	Student Initials	Supervising Professor Initial	5
	 The s with t 	tudent/supervising professor he fall (August 31 st) Student	Compact will be reviewed yearly and s Semi-Annual Evaluation.	submitted
		Student Initials	Supervising Professor Initial	5
	 The s either evalu 	upervising professor, RSC, ar physically, by teleconferenc ation meeting.	nd the student are required to be in at e, or by videoconference at the semi-a	tendance Innual

	SEMI-ANNUAL STUDENT EVALUATION CHECKLIST
	Evaluation Process Instructions
er	mi-annual Evaluation Process:
]	Student completes information request on page 1, Sections I-III, and the Student Progress Repor 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 and digitally signs and dates Section V.
	Student and Supervising Professor meet to review the completed evaluation and the student digitally signs and dates Section V.
	Student arranges for a group meeting with the Research Supervising Committee (RSC) and forwards a copy of the RSC members to review prior to the group meeting. All members must be present at the group meeting either in person or via teleconference or video conference, no exceptions.
	Student obtains the required digital signatures and dates on the Student Progress Report form during the group meeting. If the RSC members do not bring their laptops with them then the student will need to e-mail to each individual member for their digital signature. Please note that digital signatures must be on one form.
	Student completed and signed Student Semi-Annual Evaluation form to the MSCI-TS Academic Coordinator.
Г	Semi-annual Student Evaluation form
	Student Progress Report form
e	
C tł	e a student has successfully met the research and manuscript requirements for graduati he MSCI-TS Program, no further semi-annual evaluations will be required.

SEMI-ANNUAL STUDENT EVALUATION					
STUDENT (Name & Credentials):	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)				
UPERVISING PROFESSOR (Name & Credentials):					
	MSCI-TS COGS Member (Name & Credentials):				
	MSCI-TS Graduate Faculty Member (Name & Credentials):				
	External Expertise Specific Faculty Member (Name & Credentials)				
 iOALS OF THE SEMI-ANNUAL STUDENT EVAI A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS) C. Provide the student with a critique of past D. Establish concrete goals to clarify performation E. Identify research and career development 	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- s). six months performance and accomplishments. ance expectations. options.				
 A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS C. Provide the student with a critique of past D. Establish concrete goals to clarify performa E. Identify research and career development 	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- s). six months performance and accomplishments. ance expectations. options.				
A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS C. Provide the student with a critique of past D. Establish concrete goals to clarify performa E. Identify research and career development	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- s). six months performance and accomplishments. ance expectations. options.				
A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS C. Provide the student with a critique of past D. Establish concrete goals to clarify performa E. Identify research and career development	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- s). six months performance and accomplishments. ance expectations. options.				
 A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS C. Provide the student with a critique of past D. Establish concrete goals to clarify performa E. Identify research and career development 	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- s). six months performance and accomplishments. ance expectations. options. nent and major accomplishments:				
 A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS C. Provide the student with a critique of past D. Establish concrete goals to clarify performa E. Identify research and career development 	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- s), six months performance and accomplishments. ance expectations. options. nent and major accomplishments:				
A. Encourage a candid conversation between B. Create a document for review by the stude TS Committee on Graduate Studies (COGS C. Provide the student with a critique of past D. Establish concrete goals to clarify performa E. Identify research and career development Section I: Student Self-Assessm Brief Overview of student's research project	LUATION PROCESS ARE TO: supervising professor(s) and student. ent's Research Supervising Committee (RSC) and by the MSCI- six months performance and accomplishments. ance expectations. options.				

 Publications (Number): _(___) Yes No If yes, please list. (Include for each listing: PubMed Number; title; author(s); journal; and volume: page number.) No • Presentations at Local/National/International Meetings (Number): () Yes If yes, please list. (Include for each listing: date; meeting, location, type, and Presentation title.) P a g e | 2 Revised: 01/31/2018

• Seminar Presentations (Local/National/International): Yes Yes No If yes, please list. (Include for each listing: date, seminar, location, type, and Presentation title.)
Honors/Awards: Yes Yes If yes, please list. (Include for each listing: date, name/title, and brief description.)
• Intramural Funding: Yes No If yes, please list. (Include for each listing: submitted and/or funded applications.)
P a g e 3 Revised: 01/31/2018

• Extramural Funding: If yes, please list. (Include for each listing: submitted and/or funded a	Yes No
• Patents: If yes, please list.	
• New areas of research or technical expertise acquired:	Yes No
If yes, please describe.	
P a g e 4	Revised: 01/31/2018

 Supervisory activity: If yes, please describe. (<i>i.e.,</i> oversight of graduate/undergraduate or summe name, academic level, and project title.) 	Yes No r Student-include
• Teaching: If yes, please describe. (<i>i.e.,</i> lectures or lab sessions, and hours-include Depa	Yes No
name, and section title.)	
• Clinical activity: If yes, please describe.	Yes No
P a g e 5	Revised: 01/31/2018

• Committee or other service activity: If yes, please describe. <i>(Indicate if you held an office.)</i>	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
P a g e 6	Revised: 01/31/2018

 Are there any obstacles to your research productivity? 	Yes No
If yes, please describe.	
	생
>	
Section II. Student Research and Other Training Pla	ans for the
Next Six (6) Months	ans for the
 Research project and professional development goals: 	
	- 5
$P a g e \mid 7$	Revised: 01/31/2018

Anticipated public	ations (indica	te project auti			
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
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Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
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Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		
Anticipated meeti	ng(s) or work	shop(s) to be	attended:		

	ang agency type of award, and
 Other professional training (e.g., course work): 	
Section III: Student Career Goals	
Section III: Student Career Goals • Describe your long-term career goals:	
Section III: Student Career Goals • Describe your long-term career goals:	
Section III: Student Career Goals Describe your long-term career goals:	
Section III: Student Career Goals • Describe your long-term career goals:	
Section III: Student Career Goals Describe your long-term career goals:	
Section III: Student Career Goals • Describe your long-term career goals:	
Section III: Student Career Goals • Describe your long-term career goals:	

 Describe what your job searching 	It further research activity or other training is needed before it is appropriate to begin rch:
When will yo	ur job search be initiated?
 Please indica and internation 	te if there are other issues that will affect your job search (<i>e.g.,</i> relocation constraint onal trainee with an assured position in home country):
Page 10	Revised: 01/31/24

Section IV: Supervising Prof Performance	essor's Ass	essment	of Studen	ťs	
Rate performance in the following areas: Overall Knowledge of: Project Literature Methods/Lab Techniques/Equipment Productivity/Quality of Work Lab Techniques	Expectations Not Achieved	Meets Expectations	Exceeds Expectations	Distinguishe	Cannot Assess
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	B	8	8	₿	
OVERALL ASSESSMENT Would you recommend student for continuation in MSCI-TS Program? Yes No What is the next level for this student? (e.g., job, additional training in this lab, additional training ir another lab)					No No
^p a g e 11				Revised	: 01/31/2018

dditional commenter	
uditional comments:	
ection V: Signatures	
Section V: Signatures (Signatures below acknowledge review of this semi-annual	evaluation.)
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MSCI-TS Program STUDENT PROGRESS R	EPORT	
STUDENT (Name & Credentials):		
SUPERVISING PROFESSOR (Name & Credentials):	Signature	Date
SUPERVISING COMMITTEE:	Signature	Data
MSCI-TS COGS Committee Member (Name & Credentials)	Signature	Date
Expertise Specific Faculty Committee Member (Name & Credentials)	Signature	Date
STUDENT (Name & Credentials):	Signature	Date
P a g e 13		Revised: 01/31/2018

MSCI-TS Program		
See MSCI-TS Handbook for detailed program requirements.		
Submission Deadlines		
Submission Deaumes.		
Manuscript Approval Research Supervising Committee (RSC) Meeting:		
Two (2) weeks prior to the student's Manuscript Approval Research (RSC) meeting.		
1 st Week of October (Fall Semester Graduation) 1 st Week of March (Spring Semester Graduation)		
Submit to Academic Coordinator for MSCI-TS COGS Monthly Meeting:		
Last Friday of October (COGS October MeetingFall Semester Graduation) Last Friday of March (COGS March MeetingSpring Semester Graduation)		
Required Documentation:		
Please e-mail the following documents as separate PDF documents to the MSCI-TS Academic Coordinator via e-mail. JPEG, WORD, or any other format <u>will not</u> be accepted.		
Manuscript Approval Form:		
All information, complete names with credentials, dates, & e-signatures are provided on the form.		
Supervising Professor's Cover Letter:		
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."		
Letter with Supervising Professor's e-signature		
Journal Dated Submission Notice:		
All Confidential information has been blacked out. (i.e. Usernames, Passwords)		
PDF 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.		
Manuscript		
Manuscript Assessment Form:		
All information, complete names with credentials, dates, & e-signatures are provided on the form.		
The form should be returned to the MSCI-TS academic coordinator via e-mail by the Supervising Professor		
Revised: 10/16/2017		

	T APPROVAL		
(Approval Signatures of Research Supervising Committee (RSC) Required)			
Student Name, Credentials:			
1anuscript Title:			
Authors (complete listing in order of appearance):			
lournal:			
Submission Date:			
E-Signatures below affirm that the student's manuscr published, will represent a significant co	ript has been reviewed, a ntribution to the literatu	approved and, in re.	
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MSCI-TS Program	
STUDENT AMENDED RESEARCH PACKET CHECKLIST	
See MSCI-TS Handbook for detailed program requirements.	
Required Documentation:	
Documentation below should be forwarded as separate PDF documents to the MSCI-TS Academic Coordinator via e-mail by the student, with the student's RSC members being copied. Adobe Digital signatures are required.	
Request to Amend MSCI-TS Student Research Project form	
Complete the form and obtain the digital signatures of the proposed Supervising Professor and/o Supervising Committee members or current members dependent upon the change(s) made.	
Submit form with required documents listed below in accordance with what change(s) are being made.	
Amending Supervising Professor	
Supervising Professor's NIH Biosketch	
Supervising Professor's Letter of Support	
Letter includes:	
Brief overview of the planned research project including the student's role/involvement i the research project.	
Statement of commitment to the student's education and training throughout the student time in the MSCI-TS Program.	
If the student is a foreign national (F-1 or J-1 visa), an agreement to provide a bi-annua statement regarding continued support for enrollment in the MSCI-TS Program.	
Supervising Professor's Digital Signature	
Amending Research Supervising Committee (RSC)	
No other documents required; unless the proposed change is not a member of the MSCI-TS Graduate Faculty. (Documents required will be obtained from the proposed member.)	
Amending Research Plan/Title:	
Supervising Professor's Letter of Support	
Letter includes:	
Brief overview of the planned research project including the student's role/involvement i the research project.	
Statement of commitment to the student's education and training throughout the student time in the MSCI-TS Program.	
If the student is a foreign national (F-1 or J-1 visa), an agreement to provide a bi-annua statement regarding continued support for enrollment in the MSCI-TS Program.	
Supervising Professor's Digital Signature	
Amended Research Plan	
Double-spaced, typewritten plan <i>(6 page limit)</i> 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)	
Research Title Only – No other documents required.	
Revised: 01/26/201	

MSCI-TS Program			
Request to Amend MSCI-TS Student Research Project			
(Adobe Digital Signature Approval of Su	pervising Committee Required)	
Student Name:	Date	<u>ا</u>	
Request to Change:			
Supervising Professor			
(Current) Supervising Professor:			
(Proposed) Supervising Professor: Department/Division: UT HEALTH E-mail Address:			
Yes, the proposed Supervising Professor is a mem No, the proposed Supervising Professor is not a m Note: MSCI-TS Graduate Faculty Appointment will be con	ber of the MSCI-TS Graduate I nember of the MSCI-TS Gradua nsidered separately by the MSCI-T	Faculty. ate Faculty. s cogs	
Research Supervising Committee (RSC)			
(Current) Supervising Committee: MSCI-TS COGS Member:			
MSCI-TS Graduate Faculty Member:			
External Expertise Specific Faculty Member:			
(Proposed) Supervising Committee: MSCI-TS COGS Member: Department/Division: UT HEALTH E-mail Address:			
MSCI-TS Graduate Faculty Member: Department/Division: UT HEALTH E-mail Address:			
UT Health or Outside E-mail Address:			
A request to change an approved research plan <u>must</u> be acco memorandum that describes to The digital signatures below indicate review and appr and/or attac Note: The signatures below should be of the Supervising Professor a request is to change eit	ompanied by the revised resea he basis for the request. oval of the requested change hed. nd/or the Supervising Committee her of these.	rch plan and a cover es as listed above that are proposed if th	
Student Name & Credentials	Signature	Date	
Supervising Professor Name & Credentials	Signature	Date	
MSCI-TS COGS RSC Member & Credentials	Signature	Date	
Graduate Faculty RSC Member & Credentials	Signature	Date	
Expertise Specific Faculty RSC Member & Credentials	Signature	Date	
		Revised: 01/26/201	

Course Descriptions

Master of Science in Clinical Investigation and Translational Science (MSCI-TS)

TSCI 5050 Introduction to Data Science

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Alex Bokov, PhD

This elective course is designed to train participants to use programing languages such as R and SQL to extract, prepare, and analyze data. This course is designed to be self-contained: statistical methods and theory relevant to analyzing large datasets will be covered with the computer-related course content providing tangible applications and motivating examples. In addition, the course will include organizational skill training and best practices needed to run a successful collaboration between researchers conducting patient oriented clinical research and the researchers in the computational fields.

TSCI 5070 Responsible Conduct of Research

2.0 Semester Credit Hours (SCH) Course Director: Kimberly Summers, PharmD and Babatunde Oyajobi, MD, PhD

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.

TSCI 5071 Patient-Oriented Clinical Research Methods-1

2.0 Semester Credit Hours (SCH) Course Director: Byeongyeob Choi, PhD

This interdisciplinary course is the first in a two-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.

TSCI 5072 Patient-Oriented Clinical Research Biostatistics-1

2.0 Semester Credit Hours (SCH) Course Directors: Jonathan Gelfond, MD, PhD

This interdisciplinary course is the first in a two-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.

TSCI 5073 Integrating Molecular Biology with Patient-Oriented Clinical Research

1.0 Semester Credit Hours (SCH) Course Directors: Teresa L. Johnson-Pais, PhD

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.

TSCI 5074 Data Management, Quality Control, and Regulatory Issues

2.0 Semester Credit Hours (SCH) Course Director: Schmidt, Susanne, PhD

This interdisciplinary course is designed to train participants in the necessary data-management and qualitycontrol 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 data-management 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 quality-assurance 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:

• 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;

- 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;
- 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.

TSCI 5075 Scientific Communication

2.0 Semester Credit Hour (SCH) Course Directors: Hai Rao, PhD

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.

TSCI 5076 Introduction to Informatics

1.0 Semester Credit Hour (SCH) (elective course) Course Director: Brad Brimhall, MD, MPH

This *elective* course is designed for students interested in information technologies in the context of clinical investigation. It offers an overview of the field of informatics applied to biomedicine, covering specific applications and general methods, issues, capabilities and limitations of informatics systems. Student teams will conceive, design, specify, implement, evaluate, and report on a software project in the domain of biomedicine. The projects will include proposal writing, peer review, and preparing final reports, as well as guest lecturers from field experts.

TSCI 5077 Practicum in Translational Science

1.0–3.0 Semester Credit Hours (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Linda McManus, PhD

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.

TSCI 5078 Introduction to Intellectual Property, Technology Transfer and Commercialization

1.0 Semester Credit Hour (SCH) (elective course) Course Director: Leonid Bunegin, BSc

This *elective* course provides an in-depth overview of the essential components encompassed in the protection of intellectual property, patents, licensing, technology transfer, and product commercialization. Content is provided through a series of lectures, assigned readings, literature reviews, class presentations, and discussions with faculty.

TSCI 5079 Practicum in Intellectual Property, Technology Transfer and Commercialization

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Leonid Bunegin, BSc

This *elective* course provides an opportunity for participation in unique clinical and translational research activities that focus on the processes involved in the protection of intellectual property and the transfer and commercialization of technology. Activities are highly individualized for each student on the basis of prior experience and research interests.

TSCI 5080 Integrating Molecular Biology with Patient Oriented Clinical Research Practicum

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Goutam Ghosh-Choudhury, PhD

This is the required practicum to TSCI 5073 (Integrating Molecular Biology with Patient-Oriented Clinical Research Practicum. This practicum is designed to provide the opportunity for highly individualized research activities for integrating molecular biology methods into patient-oriented clinical research.

TSCI 6001 Introduction to Translational Science

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Philip LoVerde, PhD and Bertha E. "Penny" Flores, RN, PhD

This *elective* course provides an in-depth overview of the essential components encompassed by translational science. Content is provided through a series of lectures, assigned readings, literature reviews, class presentations, and discussions with faculty

TSCI 6060 Patient-Oriented Clinical Research Methods-2

2.0 Semester Credit Hours (SCH) Prerequisite: Patient-Oriented Clinical Research Methods-1 Course Director: TBA

This interdisciplinary course is the second in a two-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.

TSCI 6061 Patient-Oriented Clinical Research Biostatistics 2

2.0 Semester Credit Hours (SCH) Prerequisite: Patient-Oriented Clinical Research Biostatistics - 1 Course Director: Jonathan Gelfond, MD, PhD

This interdisciplinary course is the second in a two-semester sequence designed to train participants in the biostatistical analysis 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) 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.

TSCI 6064 Grantsmanship and Peer Review

1.0 Semester Credit Hour (SCH) (elective course) Course Director: Linda McManus, PhD

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 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.

TSCI 6065 Health Services Research

2.0 Semester Credit Hours (SCH) Prerequisite: Patient-Oriented Clinical Research Methods-1 and Patient-Oriented Clinical Research Methods-2 Course Director: Polly Noel, PhD and Helen Hazuda, PhD

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

TSCI 6067 Genomic Healthcare

1.0 Semester Credit Hour (SCH) (elective course) Course Director: Donna Lehman, PhD

This *elective* course prepares students to integrate genomic and other omics technology into patient care and clinical research. It begins with an introduction to genomics and overview of omics technologies. Students will explore the different resources of genomic information and have opportunities to apply these resources to keep abreast of current knowledge in their health topic of interest including the ethical individual and

societal challenges ahead. Genomics in cancers is an active area in personalized medicine, and this topic will be discussed by a local cancer genomics expert. The course will also provide an introduction and overview of current applications of gene therapeutics to a variety of disorders. By the end of the course, students will have a working knowledge of the human genome and the tools for integrating this information into clinical research as well as conveying it to patients.

TSCI 6069 Statistical Issues, Planning, and Analysis of Contemporary Clinical Trials

2.0 Semester Credit Hour (SCH) (elective course) Prerequisite: Patient-Oriented Clinical Research Biostatistics – 1 and Patient-Oriented Clinical Research Biostatistics – 2 Course Director: Jonathan Gelfond, MD, PhD

This *elective* course will serve as an in-depth survey of the various clinical trial designs, analysis, and regulatory issues. Students will learn to apply statistical principles in designing clinical trials to minimize risk to patients while maximizing generalizable discovery. Specific topics include Phase I-V studies, adaptive designs, longitudinal and survival studies. Students will learn to specify the primary outcome and to estimate the required sample size for common trial designs. Clinical trial design and analysis is often complicated by idiosyncrasies such as missing data, and the methodology for handling these will be covered.

TSCI 6070 Biostatistics Methods for Longitudinal Studies

2.5 Semester Credit Hour (SCH) (elective course) Prerequisite: Patient-Oriented Clinical Research Biostatistics – 1 and Patient-Oriented Clinical Research Biostatistics – 2 Course Director: Chen-Pin Wang, PhD

This *elective* course will discuss a broad range of statistical techniques for deriving statistical inference from longitudinal studies. Main topics include design of longitudinal studies (power analyses and sample size estimation), analyses of repeated measured outcomes (continuous and discrete), analyses of time-to-event outcomes, techniques to address challenges associated with missing data and confounding data, and rigorous casual modeling approaches. Students will learn to identify feasible and efficient statistical designs for longitudinal studies and to conduct rigorous and robust statistical methods to analyze data from longitudinal studies. The goal is to develop students' biostatistical competencies in conducting high-quality longitudinal studies in medical research.

TSCI 6097 Research

1.0 – 3.0 Semester Credit Hours (SCH) Prerequisite: An approved Supervising Professor, Supervising Committee, and research project in the MSCI-TS program. Course Director: Donald M. Dougherty, PhD

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 a manuscript. After MSCI-TS COGS approval of the research project, students will take 3 semester credit hours of research during each semester of the Master of Science in Clinical Investigation and Translational Science Degree Program.

TSCI 6098 Thesis

1.0 Semester Credit Hours (SCH) Prerequisite: An approved Supervising Professor, Supervising Committee, and research project in the MSCI-TS program. Course Director: Donald M. Dougherty, PhD

Registration for one semester is required of MSCI-TS degree candidates.

TSCI 6100 Practicum in IACUC Procedures

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Rodolfo Trevino, MS, CPIA

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 UTHSCSA. Course objectives are achieved through a combination of readings, monthly attendance at selected IACUC meetings, and discussions with faculty.

TSCI 6101 Topics in Translational Science

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Christopher Frei, PharmD, MSc

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

TSCI 6102 Practicum in IRB Procedures

1.0 Semester Credit Hour (SCH) (elective course) *Prerequisite: Consent of the Course Director* Course Director: Meyad Baghezza, BA, CIP

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 UTHSCSA. Course objectives are achieved through a combination of readings, monthly attendance at selected IRB meetings, and discussions with faculty.

MSCI-TS Contact Information

Donald M. Dougherty, PhD **Program Director** 210-567-4304 (voice) <u>Doughertyd@uthscsa.edu</u>

Alex Machuca Academic Programs Coordinator IIMS/Office of Research Education and Mentoring Main Campus, 7.742F, MED 210-567-4304 (voice) Machuca@uthscsa.edu

> MSCI-TS Program UT Health at San Antonio 7703 Floyd Curl Drive San Antonio, Texas 78229-3900

This educational program is supported in part by a grant provided by the National Center for Advancing Translational Science of the National Institutes of Health

(UL1 TR002645)

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 • Practicum in Translational Science • Introduction to Translational Science • Practicum in IACUC Procedures • Topics in Translational Science • Practicum in IRB Procedures • Selected Topics in Advanced Research Ethics • 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

Practicum in Translational Science Introduction to Translational Science • Practicum in IACUC Procedures • Topics in Translational Science • Practicum in IRB Procedures

 Selected Topics in Advanced Research Ethics
 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
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Data Management, Quality Control, and Regulatory Issues • Grantsmanship and Peer Review • Health Services Research • Instrument Validation and Development • Genetics and Genetic Epidemiology

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Instrument Validation and Development
Genetics and Genetic Epidemiology
Cross Cultural

Adaptation of Research Instruments in IACUC Procedures • Topics in Research Ethics • Responsible C Clinical Research • Patient-Orie Integrating Molecular Biology with Issues • Grantsmanship and Peer F and Genetic Epidemiology • Cros Introduction to Translational Scienc



to Translational Science • Practicum res • Selected Topics in Advanced sponsible Conduct of Patient-Oriented ed Clinical Research Biostatistics • ment, Quality Control, and Regulatory alidation and Development • Genetics Practicum in Translational Science • nslational Science • Practicum in IRB

Procedures • Selected Topics in Advanced Research Ethics • Responsible Conduct of Patient-Oriented Clinical Research • Patient-Oriented Clinical Research • Patient-Oriented Clinical Research Methods • Patient-Oriented