

GRADUATE PROGRAM IN CLINICAL AND TRANSLATIONAL SCIENCE

Program Guide
2021-2022

NOTE: Due to COVID-19 restrictions, some timelines, deadlines and requirements may be modified.



Graduate School of
Biomedical Sciences

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The requirements described in these guidelines may be amended or altered by the Graduate Program. Note that GSBS-wide policies supersede program specific policies.

In 1999, responding to the clear need for renewal of clinical research training and to the NIH-led call for the development of rigorous training in clinical research disciplines, the Clinical and Translational Science (CTS) Program of the Tufts University Graduate School of Biomedical Sciences became the nation's first MS/PhD program in clinical research in a biomedical graduate school.

A decade after the initiation of the Tufts University Graduate School Clinical Research Program, Tufts University was awarded an NIH Clinical and Translational Science Award. This allowed creation of Tufts Clinical and Translational Science Institute (CTSI), aimed at taking the fullest possible advantage of the extraordinary array of disciplines, novel methods, and opportunities across Tufts University and its affiliates, to generate innovative and impactful research. Education and career development were understood to have a central role in supporting the mission of the CTSI, and Tufts CTSI was created with the GSBS Clinical and Translational Graduate Program as a central resource. The program leadership realized that in its objective to transform research across Tufts University and its affiliates and partners, it had to clearly reflect the core philosophy, content, and processes in its research education and training programs. The educational programs had to reflect the commitment to full-spectrum translational research objectives—from bench to bedside to practice, to public benefit and policy—and back again, across each translational step.

The emphasis on the full spectrum of translational research in three concentrations (Clinical Discovery and Investigation, Clinical Effectiveness, and Practice to Policy Translational Research) that span T1-T4 research reflect the integrated approach. In addition, the CTS Program strives to support scholars through junior faculty scholar awards and pre- and post-doctoral training fellowships.

The CTS Graduate Program continues to reflect the core values, mission, and methods of the GSBS and the CTSI and continues to support training and career development of translational researchers.

David M. Kent, MD, MSc
Program Director

The purpose of this Clinical and Translational Science (CTS) Program Guide is to help students manage their academic careers within the CTS Graduate Program. The Guide, together with the GSBS Student Handbook (<https://gsbs.tufts.edu/studentLife/StudentHandbook>) and the GSBS Catalog (<https://gsbs.tufts.edu/studentLife/school-Catalogs>) serves to orient new students as well as guide students throughout the year. Students should refer to this Guide for specific program requirements, significant events, and essential contacts. The Guide aims to streamline common processes for our graduate students and outlines deadlines and deliverables for CTS graduate students. We also recommend that students go to the GSBS CTS website (<https://GSBS.tufts.edu/academics/CTS>) for information about the program.

The Guide has easily identified sections for quicker access to information. Students may also access the Guide online to benefit from web links, attachments, and current information.

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The Clinical and Translational Science (CTS) Program offers an in-person Certificate in CTS and an online Certificate in Health Economics and Outcomes Research as well as two degree programs, MS and PhD.

CTS Certificate Program

The Certificate Program has many of the same course work as the MS Program and is compatible with a part-time commitment of one academic year of study. The student develops a brief research protocol and conducts mentored research in the Spring semester.

Health Economics and Outcomes Research Certificate Program

The Health Economics and Outcomes Research (HEOR) Certificate Program is an asynchronous, online program. Students take three online courses as a basic introduction to HEOR. The HEOR Certificate program is designed to also include a face-to-face symposium at the end of the second semester, with the presentation of culminating projects and opportunities for networking with fellow students and program faculty. Credits from the HEOR Certificate Program do not transfer into the degree programs.

Master's Program

The Master's Program is a two year, full-time program. Students take core courses essential to developing the necessary competencies to become independent researchers and leaders in their fields of research including Principles of Epidemiology, Study Design, Scientific and Grant Writing, and Biostatistics. The MS Program offers students the option of choosing among three areas of concentration: Clinical Discovery and Investigation, Clinical Effectiveness Research, and Practice to Policy Translational Research.

PhD Program

The PhD Program is typically completed in approximately four and a half years, although the exact timeframe depends on the student. Students in the PhD Program develop the necessary competencies for a career in academic medicine that involves significant translational research.

There are two ways to gain admission to the PhD program. A master's degree candidate may request permission to sit for the PhD qualifying exam from the Advisory Committee, which reviews the candidate's academic record and overall contributions to the Master's Graduate Program before making a decision. Alternatively, individuals who already have a Master's degree in Clinical & Translational Science may apply to enter the PhD Program directly.

DIDACTIC COURSE REQUIREMENTS

Required and Elective Courses

The CTS Graduate Program curriculum is designed to introduce students to all phases and components of the research process. The curriculum aims to guide student development through a mentored research experience, where the student is exposed to a variety of dedicated researchers and faculty, and diverse research projects within Tufts University, Tufts Medical Center, and Tufts CTSI affiliates.

Students are required to take core courses essential to developing the necessary competencies to become independent researchers, enabling them to critically evaluate and analyze data, design rigorous studies, and develop new methods.

Remediation mechanisms are at the discretion of program Faculty and course directors and should be clearly stated in the course syllabus. Remediation is offered only to failing students and for them to only achieve the minimum passing grade of B- or S as applicable.

Requirements and course descriptions are available in the GSBS Catalog, the official resource for all of the CTS Graduate Programs: (<https://gsbs.tufts.edu/studentLife/schoolCatalogs>).

The online student registration system (<https://sis.uit.tufts.edu>) provides information on core and elective courses being offered, faculty instructor/s, locations and time/date.

Please note that Concentration electives are not offered on an annual basis. Each semester, a survey of students determines the elective course/s offered. In addition to CTS Elective Courses, students may, with the permission of the CTS Program Director, cross register for courses offered at Tufts University and several area universities by completing the Cross-Registration Request Form (<https://GSBS.tufts.edu/studentLife/currentStudents/forms>).

In addition to the core courses, MS and PhD students may elect a concentration to develop a greater depth of knowledge and skills in a selected area:

Clinical Discovery and Investigation (T1-T2): This concentration provides collaborative interdisciplinary training in basic biomedical and clinical research methodologies. This includes the translation of the basic molecular pathophysiology of diseases to clinically meaningful applications as well as the full range of patient-oriented clinical research (randomized controlled trials, and Phase I, II, and III trials).

Evidence-Based Clinical Effectiveness Research (T3): This concentration focuses on learning about the methodologies and applications of systematic review and meta-analysis, and in the development of clinical practice guidelines as the tools to practice evidence-based healthcare.

Health Services and Outcomes Research (T4): This concentration emphasizes application of a variety of methods to the investigation of population health improvement and the organization, delivery, financing, and outcomes of health care services.

Students work with the Concentration Leader to identify electives or projects to develop the competencies for that

area. Students in the Clinical and Translational Science Graduate Program may elect one of three concentrations. The table below shows each elective course and the Concentration(s) to which it applies.

Students in the HEOR Certificate Program must take three online courses. The first semester will feature the Introduction to HEOR course. The courses in Real World Evidence and Health Technology Assessment are offered in the second semester.

DIDACTIC COURSE REQUIREMENTS

Concentrations

ELECTIVE COURSES	CONCENTRATIONS		
	Clinical Discovery and Investigation (T1-T2)	Clinical Effectiveness Research (T3)	Practice to Policy Translational Research (T4)
Translational & Molecular Epidemiology (0.5)	X	X	
Bridging the Bench to Bedside Gap (0.5)	X		
Predictive Models for Health Outcomes (1)		X	X
Concentration Practicum (variable)	X	X	X
Advanced Topics in Biostatistics (0.5)	X	X	X
Principles of Drug Development (1)	X	X	
Health Economics (0.5)	X	X	X
Special Topics in Clinical Trials (0.5)	X	X	
Introduction to Decision Analyses (0.5)		X	X
Comparative Effectiveness Research Survey (1)		X	X
Applying Quality Improvement Methods in Healthcare and Public Health (1)			X
Machine Learning in Predictive Medicine (1)	X	X	
EXAMPLES OF CROSS REGISTRATION ELECTIVES			
TUFTS PUBLIC HEALTH AND PROFESSIONAL DEGREES			
Clinical Epidemiology of Cardiovascular Disease	X	X	X
Epidemiology of Zoonotic Infection	X	X	X
Cancer Epidemiology & Prevention	X	X	X
TUFTS SCHOOL OF ENGINEERING			
Introduction to Computer Science	X	X	X
Data Structures	X	X	
Computational Biology	X	X	
TUFTS FRIEDMAN SCHOOL OF NUTRITION			
Dietary Antioxidants & Degenerative Diseases	X	X	
Applied Nutritional Biochemistry	X		
BRANDEIS UNIVERSITY			
Issues in National Health Policy		X	X
Quality & Performance Measurement in HealthCare	X	X	X
Economics of Behavioral Health	X	X	X
NORTHEASTERN UNIVERSITY COLLEGE OF SCIENCE*			
Drug Design, Evaluation and Development	X	X	
The Business of Biotechnology	X	X	X
Management Skills in Biotechnology	X		
Introduction to Regulatory Science	X	X	X

*<http://www.cps.neu.edu/degree-programs/graduate/masters-degrees/masters-regulatory-affairs.php>

THESIS FACULTY MENTORS

The Graduate Program incorporates faculty mentoring for all matriculated students enrolled in the CTS Certificate, MS, and PhD programs. The process by which students select each type of faculty mentor is described below. With the exception of the statistical mentor, it is the responsibility of the student to ask a faculty member if they are willing to serve as a mentor. Faculty members may decline if they feel they do not have adequate expertise or have too many committee responsibilities. Upon selection of Mentors, students should contact the Graduate Program Manager, who will provide the Mentors with the Mentor Agreement and Guidelines.

- CTS Certificate students are required to have one mentor: a Project Mentor.
- MS students are required to have a Thesis Advisory Committee composed of at least three mentors: a Project Mentor, a Program Mentor, and a Statistical Mentor. Typically, a Project or Program Mentor serves as the Thesis Chair.
- PhD students are required to have a Thesis Advisory Committee composed of a Project Mentor, a Program Mentor, a Statistical Mentor, and a Thesis Chair. Also, the PhD Thesis Defense Committee includes an External Advisor.

Mentors are further explained by the type of student activities they provide, career development (Program Mentor), and specific research projects (Project Mentor).

Project Mentors

Project Mentors are faculty members who have particular skills and resources that are relevant to a student's clinical research focus.

(CTS Certificate Students)

The Project Mentor, who provides the mentored research experience during the Spring Semester, is the only required mentor for CTS certificate students and should be identified early in the Fall Semester, if not earlier. The student's mentored research project must be completed in the Spring Semester.

There are no specific mentor requirements for students enrolled in the HEOR Certificate Program.

(MS and PhD Students)

Selection of a student's Project Mentor will be the joint responsibility of the student, his or her Program Mentor, and the Program Director. Project Mentors should be identified early in the Fall semester of the first year of the program.

Program Mentors

(MS and PhD Students)

Each MS and PhD student has a designated Program Mentor who is responsible for ensuring that the student's experience in the Program is optimal and provides the necessary support for the student's professional and career development. Beyond the training program role, it is

anticipated that these faculty members will be exceptional role models for their students; thus, demonstrating by their approach to research, the workplace behaviors and commitment to ethical conduct that will guide the student well into the decades beyond graduation. In many cases, the Program Mentor is assigned by a student's individual training program; Program Mentors should be identified early in the Fall semester of the first year of the program.

Statistical Mentors

(CTS Certificate Students)

Although CTS Certificate students are not assigned a Statistical Mentor for their required research project, they have access to ad hoc statistical support from the core Graduate Program Statistical Mentors.

(MS Students and PhD Students)

Statistical Mentors are faculty trained in biostatistical methods who work with the students in the development and conduct of thesis research. By the beginning of the Fall semester, a Statistical Mentor will be assigned to every student. The primary responsibility of the Statistical Mentor is to provide guidance on the analytic and data management components of the thesis. While students are expected to conduct their own statistical analyses, the Statistical Mentor assists the student in establishing the optimal analytic approach, reviewing study results, and providing general guidance on statistical methods.

Thesis Chair

(MS and PhD students)

As students progress in the MS or PhD program, they will select a Thesis Chair for their committees. Often, a student's Project Mentor becomes the Thesis Chair. The Thesis Chair must be a faculty member of the Graduate School of Biomedical Sciences.

The major responsibilities of the Thesis Chair are to provide timely advice and critical feedback regarding the design and execution of the research, and to advocate for and represent the student at Advisory Committee meetings. Each semester, the Thesis Chair must provide an academic grade in mentored research to the GSBS; therefore, the Thesis Chair must have a GSBS faculty appointment.

Thesis Committee

(MS and PhD Students)

A student's Thesis Committee consists of their mentors; the Thesis Chair presides over the committee. The Thesis Committee, both collectively and individually, is responsible for reviewing and approving the student's progression from identification of a project, development of a research protocol and thesis proposal, and progress throughout the conduct and completion of the thesis research.

THESIS FACULTY MENTORS

External Advisor

(PhD Students Only)

An External Advisor is an esteemed academic or industry field expert that is not connected to the thesis. This mentor contributes a non-biased opinion to the strengths and weakness of the thesis and if the PhD thesis qualifies to be orally defended. The thesis advisory committee members decide whether the outside examiner proposed by the student is suitable. This decision should be made unanimously, and the committee needs to consider potential conflicts of interest.

RESEARCH REQUIREMENTS

The fundamental precept of the CTS Graduate Program is for the student to complete a comprehensive independent clinical research project. This research project is cultivated from a student's interests, background, and certain practical considerations such as access to resources and mentor relationships. As part of the Admissions process, students identify areas of interest and their background in relation to areas of clinical research.

Student papers published prior to matriculation into the CTS Graduate Program may not be submitted as part of a thesis. The majority of the student's research must be completed after matriculation under the supervision of a CTS Graduate Program faculty member.

With approval from their mentor, CTS Certificate students are required to develop and complete a final project (publishable manuscript/brief report, proposal for pilot project, etc.) by the end of the Spring semester.

To complete the Master's Program, it is mandatory for the student to orally present his/her thesis to the Thesis Committee and the Advisory Committee members for approval.

To complete the PhD Program, it is mandatory for a PhD candidate to orally present his/her thesis to the Thesis Committee, the Advisory Committee members, and invited guests for approval.

First year MS and CTS certificate students will present their research as poster presentations, while both Master's and PhD graduating students will orally present their theses research at the Annual CTS Graduate Program Symposium. The purpose of the Thesis is to demonstrate research competence as a culminating project of the Clinical and Translational Science Graduate Program.

HEOR Certificate students will present their work during the culminating symposium during the second semester.

Thesis Advisory Committee (TAC) Evaluation Form and Training and Career Goals Progress Report

Each semester students are required to meet with their Thesis Committee Advisors, complete a CTS TAC Evaluation Form, and submit it to the GSBS Registrar (GSBS-Registrar@tufts.edu) and the Program Coordinator within 10 days of the Thesis Committee Meeting. The Thesis Advisory Committee submits grades for students' Mentored Research. CTS Certificate students are not required to submit a TAC Evaluation Form but may be asked to by their mentors in order to assign a mentored research grade.

In most circumstances, two meetings a year, one in the fall semester and one in the spring semester, will be adequate to evaluate the student's progress in the graduate research course. If the TAC deems it necessary, however, they may require interim meetings to ensure that the student receives proper guidance and support.

At each TAC meeting, the committee, PI and student should discuss and decide on expectations to be met prior the next meeting and set a date for that meeting. Interim

committee meetings for any reason other than granting permission to defend may not be scheduled any sooner than two months since the last meeting. The TAC can choose not to provide a grade at an interim meeting as long as a regular meeting is held within the term's timeframe. However, at the discretion of the TAC, a grade may be assigned at an interim meeting. Only one grade will be permitted each term.

In preparation for Thesis Committee Meetings, students must complete a Training and Career Goals Progress Report once a year prior to the meeting. CTS Certificate students should also complete this form and discuss it with their Mentors. This requirement is designed for a student to assess their academic experience as well as professional development.

For more information and updated forms, see <https://GSBS.tufts.edu/studentLife/currentStudents/forms>. Students should download the most recent version of these forms for every submission.

MS Thesis Proposal Procedures

NOTE: Please refer to the 1st year calendar below for key deadlines.

Under the guidance and direction of their respective Thesis Committees, all first year CTS Graduate Program students must prepare a brief (4-6 page) thesis proposal for review and approval by the CTS Graduate Program Advisory Committee.

The thesis project is intended to provide students an opportunity to apply CTS Graduate Program coursework and faculty mentorship to their specific research interests. The thesis project may be one of the student's mentored research projects or a new self-initiated project; however, the thesis hypothesis and subsequent work must be explicitly self-initiated and independent. While it is appropriate to use an existing dataset, it is not appropriate for the mentored research/thesis project to be a derivative of an existing research initiative where the hypothesis has been established and on-going work is needed to maintain the research.

MS Thesis Proposal Required Content

The thesis proposal must present a research plan that addresses the following topics.

1. **Introduction:** a brief description of the background, opportunities and knowledge gaps relevant to your research question of interest.
 - b. Support your rationale for the proposed research with references to specific scientific literature.
 - c. Discuss the significance of the research to 1) increasing scientific knowledge and 2) improving public health. Discuss opportunities, gaps, and obstacles in your field and demonstrate your familiarity with the field and knowledge about the proposed research being done, referring to relevant scientific literature.

RESEARCH REQUIREMENTS

- d. Be sure to conclude this section with your Specific Aim(s): The basic research question, including a clear statement of the hypothesis and proposed summary approach to test the hypothesis and address the knowledge gap of interest.
2. Study Design and Methods: a concise statement of the overall approach that addresses:
 - a. Study design
 - b. Description of study population/data set
 - c. Description of primary and secondary endpoints
 - d. Data collection procedures
 - e. Power/sample size calculation
 - f. Statistical analysis plan: Discuss your plans for analysis. Key questions to address: What are the independent and dependent variables? What analytic strategy will be applied given the variables of interest and number of observations (study N)? What multivariable approaches will be considered? Are data missing? Will missing data hamper the planned analysis? Who will perform each part of the analysis? (Justify help needed for any analysis.)
 - g. Human Subjects Protections: Discuss any issues regarding the protection of human subjects. Collection of new data requires prior approval from the Tufts Medical Center IRB. Use of existing datasets also requires IRB assurances regarding use of the information.
 3. Implementation: summarize your plans to complete this project and identify potential barriers and proposed solutions.
 - a. Timeline: Present a timeline (generally no more than 10 months) to complete your research and prepare your final thesis for review by the Advisory Committee after obtaining full approval from all thesis mentors. Consider specific research tasks within your thesis project and the time required to complete those tasks. Key questions to address: What is the time frame for IRB review and approval? When will you collect, clean, and analyze data, and write the manuscript? This will take longer than you think, so please plan carefully. The final version of your thesis must be submitted to the CTS Program Advisory Committee for review and approval by next March in order to qualify for May graduation.
 - b. Feasibility of study implementation: If proposed work involves existing datasets, are the datasets accessible? If not, what has to be done to secure access? If plan entails collecting data, discuss the timeframe in which the work will be completed. Key questions to address: What resources will you have to conduct the study? Will you be able to complete your thesis work yourself, or will you require additional resources and personnel to aid

you in the completion of your work?

4. Stakeholder Engagement Plan

All thesis proposals must include a stakeholder engagement plan. The plan should highlight one or more stakeholder groups and explain how their feedback will shape your thesis research. The stakeholder plan is expected to include additional elements, although it is not expected that all students will implement their full stakeholder engagement scheme as part of their thesis work. All students must at a minimum reach out to one or more stakeholder groups. Using the template provided by CTS-566 (included in Box folder), this brief plan should (1) identify the key/potential stakeholders and describe why their input would be beneficial; (2) describe how stakeholders would be engaged in the design and conduct the project; (3) describe how the outcomes would be relevant to the stakeholders and how the results will be disseminated to stakeholder groups. For students conducting research where stakeholder engagement is critical to your thesis, a more robust stakeholder engagement plan should be developed. For assistance with the stakeholder engagement plan and reaching out to stakeholders, please contact Robert Sege, MD, PhD. IMPORTANT NOTE: This section will be reviewed by members of the Tufts CTSI stakeholder expert panel; it should be clearly written with minimal jargon. Be sure to indicate clearly which parts of the plan actually will be performed as part of the thesis project.

5. Strengths and Limitations

- a. What are the most important potential limitations to your study? How are these limitations likely to affect the interpretation of your results? Are there any possible solutions to these issues?
- b. Consider briefly listing the priority strengths of your approach.

6. Significance

Consider how your research will advance your field. How will it fill knowledge or address opportunities or roadblocks in the field? How will it improve health through science, by leading to cures, treatments, or preventions for human disease?

7. Project Narrative

A brief (2-3 sentences) description of your project that describes its relevance to translational science. It should be written in plain language and be understandable to a lay audience.

MS Thesis Proposal Review and Approval Procedures

The CTS Advisory Committee provides oversight and executive decisions for the entire Graduate Program. A main function of the Advisory Committee is to carefully monitor the academic progress and career development of each student with an emphasis on ensuring appropriate mentor relationships. The Advisory Committee consists of appoint-

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ed faculty members who, among other advisory committee responsibilities, evaluate and approve of clinical research submissions (progress reports, thesis proposals, and final thesis). The entire Advisory Committee reviews each clinical research project, though selected committee members are assigned as primary reviewers to provide a thorough critique of the submitted progress report or thesis project.

Prior to the thesis proposal deadline date, students must allow sufficient time for their Thesis Committee members to review, comment, and sign-off on their thesis proposal. The thesis proposal must be submitted electronically with the TAC Evaluation Form, which includes signatures of the entire Thesis Committee indicating their approval of the submitted thesis proposal, by the deadline to the CTS Graduate Program Manager.

The Thesis Chair or a faculty mentor presents the research project at these meetings. The CTS Advisory Committee will review the thesis proposals. The CTS Graduate Program Manager will communicate the Committee's decisions and/or recommendations for revisions to the students immediately following the meeting. Below are the potential outcomes of the CTS Program Advisory Committee review.

Approved	No changes necessary. Student may proceed with research under the guidance of his/her Thesis Committee.
Approved with minor changes	Changes must be incorporated per the recommendation of the CTS Program Advisory Committee. The student's Thesis Committee must review, approve, and sign off on the revised proposal and submit a copy of it with an updated coversheet to the Program Manager.
Not approved at this time	Significant changes required. Student must review recommendations of the CTS Program Advisory Committee with his/her Thesis Committee and submit a revised thesis proposal and updated coversheet for review at a future CTS Advisory Committee meeting.

MS Thesis Review and Approval Procedures

The Clinical and Translational Science Advisory Committee reviews the thesis in much the manner described above regarding thesis proposals. The Thesis Chair or a faculty mentor briefly introduces the student and the thesis at these meetings. The entire Advisory Committee reviews each thesis, though selected committee members are assigned as primary reviewers. The potential outcomes are as described above.

MS Thesis Defense

Upon recommendation of the Thesis Committee, the student will submit his/her thesis to the CTS Graduate Program Office for approval by the Advisory Committee at

least one week before the meeting. During the Advisory Committee meeting in which the thesis is reviewed, the student will orally defend his/her thesis with a ten-minute presentation and 10-minutes for questions. The MS thesis defense is a closed session with the Advisory Committee, Thesis Committee, and student.

PHD QUALIFYING EXAM AND THESIS REQUIREMENTS

PhD Qualifying Exam

The Qualifying Exam typically consists of two parts: 1) a general competency exam and 2) a written study protocol with an oral presentation as described below. The Qualifying Exam Committee has the discretion to propose that the Graduate Program Advisory Committee waive components of the exam based on a student's demonstrated mastery of competencies. Students typically take the qualifying exam after completing the first year curriculum.

1. General competency exam

Candidates are given a series of problems to be answered (written response) over a two day period. Material presented will be representative of the common knowledge base and study design skills required of all successful graduates of the program. Access to a computer for analyses may be required. The exam consists of problems based on the core curriculum.

Information on the general topics to be covered on the written examination will be provided to the candidate at least 30 days prior to the examination. Details of the exam will be determined by the Qualifying Exam Committee and approved by the CTS Program Advisory Committee.

2. Written protocol

The candidate will select from a prepared list of substantive issues in the candidate's field of study and generate a written protocol, similar to an NIH grant application that contains the following components:

- a. a summary statement (approximately 1 page) indicating the research question(s), the specific hypotheses to be tested, the study design, sample, methods of analysis and implications of the research;
- b. a synthesis of the current status of research on the subject, the rationale for the hypotheses and/or methodological approaches proposed, and the potential significance of the results for clinical practice and/or health policy (approximately 2-3 pages); and
- c. a detailed description of a proposed study protocol consisting of information about the study design, sampling methods, methods of measurement, data collection, data analysis and interpretation of results, and methodological strengths and weaknesses (approximately 2-3 pages).

The candidate must create a protocol that is unique and does not include research from pre-identified research projects or pursue concepts, ideas, methodology that may be applied to his or her thesis. All work must be original, generated without faculty assistance, and must be different from prior projects. General guidelines on the expectations for the written protocol and the format of the final report will be provided to the candidate at least 30 days prior to when the examination is given.

Candidates are allowed 2 weeks to complete a 5-10 page protocol. Subsequent to the submission of the report, the candidate will need to schedule a date and time with the Qualifying Exam Subcommittee to provide a short oral presentation and answer questions. Questions addressed will be on specifics of the work and general knowledge in Clinical and Translational Science.

If a candidate has been awarded a grant to support their independent research, the candidate may request to use their independent grant for the written protocol. If a MD/PhD candidate prepares a NIH F30 or F31 application that is submissible to NIH, the MD/PhD candidate may request to use their F grant application for the written protocol. Only upon approval by the Qualifying Exam Committee and the Advisory Committee will this exception be granted.

PhD Thesis Proposal

Within three months after passing the qualifying exam, students must present a thesis proposal, in the format of a research grant, to the CTS Program Advisory Committee with the prior approval of the student's Thesis Committee. This proposal must be 5-10 pages single-spaced and should state clearly the background and significance of the proposed work, preliminary data, aims and hypotheses, study design, analysis plan, stakeholder and community engagement plan, and predicted time to completion of research.

In addition, the proposal should provide a clear timeline for project components including intermediate goals toward completion of the thesis. Appropriate references should be provided. Appendices of supporting materials are allowed. Thesis proposals are evaluated based on the originality and publication potential of the research, integrity of the proposed methodological and analytic work, the magnitude of the contribution to the field of research and the final quality of the written proposal.

PhD Thesis

Once the proposal is approved, a doctoral student is expected to undertake a thesis project that will represent a novel and substantial contribution to the chosen field of endeavor. The project must be of the student's own design, and the student must be largely responsible for its completion. Ideally, the thesis project will focus on a single, important research issue. In unusual circumstances, the thesis project may consist of a series of smaller related studies designed to address a particular clinical or methodological problem.

Generally, the thesis is expected to result in at least three published manuscripts, but it is not required that the student have published, or even submitted for publication, to receive approval for the thesis. These manuscripts may be derived from the design, methods, or results of the paper or from an innovative review of the literature.

When a student receives permission, he/she should make an appointment to meet with the Associate Dean. Students will receive instructions on all aspects of the process used

PHD QUALIFYING EXAM AND THESIS REQUIREMENTS

to complete the degree, thesis formatting guidelines and information about Commencement Ceremonies at Tufts University.

PhD Thesis Defense

Upon recommendation of the Thesis Committee, the student will submit a request to the CTS Graduate Program Office to submit the thesis for approval by the Advisory Committee. During the Advisory Committee meeting in which the thesis is reviewed, the Thesis Committee members and doctoral candidate should be available by phone or in-person to answer questions. The thesis must be approved by the Advisory Committee prior to the scheduled oral defense. Chaired by the Thesis Chair, the defense shall consist of an oral presentation on the thesis research. After the student makes the oral defense, the Thesis Chair shall preside over a session during which the student may be questioned about the research. The Thesis Committee shall be given precedence for questions, followed by others in attendance.

The oral thesis defense is the culmination of the thesis process and consists of both a public presentation of approximately 45-60 minutes, followed by a closed discussion period with the committee and outside examiner. The public presentation is the opportunity for the student's lab and the GSBS community at large to hear the research. Consequently, the ideal format is for in-person public presentations is as follows:

- In Boston for students in Boston or Medford labs
- In Portland for students in Maine Medical Center Research Institute Labs
- In Bar Harbor for students in Jackson Labs

However, a fully remote (via Zoom) public presentation is acceptable.

For those students who may be working at affiliated (non-Tufts/MMCRI/JAX) labs, the defense should take place at the location the student was originally placed. In-person public presentations should also be available via videoconferencing for faculty and students on different campuses.

It is preferable that all members of the Thesis Advisory Committee (TAC) plus the approved outside examiner be physically present at both the public presentation and closed discussion. However, if necessary and unavoidable, one or more committee members may be remote for the presentation and discussion.

MS AND PHD STUDENT RESEARCH RESPONSIBILITIES

THESIS REQUIREMENTS

It is the student's responsibility to lead the research project and in many cases learn the role of the Principal Investigator. It is expected that the student reports research activities and results, demonstrates excellent and frequent communication among colleagues, and adheres to ongoing reporting requirements with their mentors, the Program Director, the Associate Director, and the CTS Advisory Committee. The purpose of these activities is to create a foundation for a long and productive career. Below is a summary of student responsibilities:

- Identify an area of interest and potential project
- Declare mentors and draft a project that will develop into a final research project for a grade and/or a publishable thesis, depending on the student's program requirements
- Establish the mentor(s) relationship
- Develop and pursue a project according to the principles discussed in the study design seminar
- Meet regularly with his/her mentor(s) as needed
- Deliver timely reports and project assessments in compliance with Graduate Program deadlines
- Adhere to ethical standards and practices, which include following the policies in the GSBS Handbook (<https://gsbs.tufts.edu/studentLife/StudentHandbook>), seeking IRB approval, proper citing of source material, completing the non-credit academic requirements, and other codes of conduct
- Be accountable to the submission deadlines and recommendations of the CTS Advisory Committee
- Comply with the GSBS deadlines specifically for registration and semester responsibilities as well as graduation requirements

Scientific manuscript writing is a key scientific competency that students are expected to develop. Students present their thesis research in the style of an original manuscript that has the potential to be submitted to a peer-reviewed biomedical research journal. In general, original research reports are between 3,000-5,000 words in length and follow the IMRAD structure (Introduction, Methods, Results, and Discussion).

The submitted thesis should consist of at least three chapters: (1) an introductory chapter that offers an expanded review of the context and literature motivating the research project; (2) the original research manuscript(s), in the format described above and (3) a final concluding chapter that ties together all of the major results, offers an overall assessment of the significance of the research, and suggests future work to address unanswered questions. There may be some overlap between the contents of the original research manuscript and the introductory and concluding chapters. Students may include an Appendix to document data collection practices, instruments, methods, or analyses that are not typically included in the body of an original research report for publication in a journal.

Adherence to this University-approved thesis format is required for successful completion of the thesis prior to graduation. Detailed formatting instructions may be found in the Thesis Formatting Instructions & Graduation Requirements document that is posted on the GSBS website: (<https://gsbs.tufts.edu/studentLife/currentStudents/forms>).

PUBLISHING REQUIREMENTS

Publishing research is an important element of the scientific research process. Students must submit their research findings to the Advisory Committee in the publishable format as a way to enhance their scholarship record in clinical research, translational research, or health policy research. One article is required for the Master's thesis (original research findings), and a minimum of three articles are required for the PhD Thesis (at least one of which must present original research findings).

For journal publication, two to three high-quality peer review journals should be identified for each planned manuscript in the initial proposal and approved by the Thesis Committee. On occasion, a paper may have been published prior to submission of the Thesis. Publishability is not necessary for acceptance of the thesis, and having a published paper in a peer-reviewed publication does not make the thesis acceptable.

Citation Guidelines

The Tufts University GSBS and the Tufts CTSI rely on grant citations as a critical performance measure when reporting annual productivity to the NIH and applying for training grants. All publications, projects, posters, patents, trademarks or other tangible outcomes resulting from services and funding at the GSBS and/or the CTSI must be cited as described below.

1. Tufts University GSBS Acknowledgement Statement

It is important for GSBS students to cite both the name of their graduate program and the GSBS. For example:

Development of a baited oral vaccine for use in reservoir-targeted strategies against Lyme disease

Debaditya Bhattacharyaa^a, Mekki Bensacib^b, Kathryn E. Lukerc^c, Gary Lukercd^d, Steven Wisdome^e, Sam R. Telfordf, Linden T. Hu^{a,b}

a Program in Molecular Microbiology, Graduate School of Graduate Biomedical Sciences, Tufts University, Boston, MA 02111, USA

b Division of Geographic Medicine and Infectious Diseases, Tufts Medical Center, Boston, MA 02111, USA

c Department of Radiology, University of Michigan Medical School, Ann Arbor, MI 48109, USA

d Department of Microbiology and Immunology, University of Michigan Medical School, Ann Arbor, MI 48109, USA

e Foodsource Lures Corp, 520 Galloway Circle, Alabaster, AL 35007, USA

f Department of Biomedical Sciences – Infectious Diseases, Cummings School of Veterinary Medicine, Tufts University, North Grafton, MA 01536, USA

2. CTSI Grant Acknowledgement Statement

(For more information see <http://www.tuftsctsi.org/about-us/how-to-cite-tufts-ctsi/>)

Use the following citation if you:

- used Tufts CTSI facilities or services (e.g., CTCRC or Core Lab; CTSI consultative services such as research design, grant editing, analysis plan, protocol development, community engagement, etc.),
- received funding through Tufts CTSI's Pilot Studies Program (i.e., Catalyst, Planning, or Methods Development),
- are a student, fellow, or scholar in the Tufts University Graduate School of Biomedical Sciences Clinical and Translational Science Graduate Program.

"The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant Number UL1TR002544. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

Use the following citation if you are a KL2 Scholar:

"The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, Award Number KL-2TR002545. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

Use the following citation if you are a TL1 Fellow:

"The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, Award Number TL-1TR002546. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

A current list of publications referencing Tufts CTSI as a source of funding is available at: <https://www.tuftsctsi.org/our-impact/publications-referencing-tufts-ctsi/>

NIH Public Access Policy

The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.

It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. For more information about the NIH Public Access Policy, please refer to the Public Access Policy site (<https://public-access.nih.gov/policy.htm>).

All publications should be submitted to PubMed Central and assigned a PubMed Central ID. For more information about PubMed Central, please refer to The NIH Manuscript Admissions System (<http://www.nihms.nih.gov/>). For instructions and personal assistance, you may visit the Tufts University Health Science Library's NIH Manuscript Submission site (<http://researchguides.library.tufts.edu/NIH-PublicAccess?hs=a>).

NON-CREDIT ACADEMIC REQUIREMENTS

CTS Annual Graduate Program Symposium

The CTS Annual Symposium is the culmination and celebration of all students' clinical research accomplishments – an event where the Graduate Program faculty and administrative staff highlight their students' achievements with great pride.

This half-day event is scheduled in May and is located in the Atrium Lobby and the Wolff Auditorium at Tufts Medical Center, 800 Washington Street, Boston, MA 02111. Graduating MS and PhD students orally present their theses research; first-year Master's, CTS Certificate, and PhD candidates present research posters. The Graduate Program also hosts a poster competition for all CTSI affiliates who present clinical and translational science research. The poster competition is held in tandem with the Graduate Program activities at the Symposium event. Faculty and administrators from Tufts Medical Center, Tufts University, CTSI affiliate hospitals and institutions as well as family, friends, and colleagues are invited to attend all activities. Traditionally, the Program Director invites a distinguished guest to attend the Symposium and present his or her research at the noontime Medical Grand Rounds at Tufts Medical Center.

Brown Bag Seminar Series

Faculty seminars are a wonderful opportunity for the students to meet many of our faculty and external speakers and to learn about their research interests. These introductions assist the students when selecting their mentors, developing a potential research topic, and ultimately introduce them to a broader range of expertise in clinical research.

These one hour seminars are informal and scheduled semi-weekly on Tuesdays or Wednesdays, mid-day. Students are expected to attend at least 50% of the seminars.

Student-Led Journal Club

Students select articles from the current literature, analyze their significance, and present them for discussion in a group, facilitated by members of the Tufts CTSI Biostatistics, Epidemiology, and Research Design (BERD) Center. Journal club is scheduled monthly at variable times during the Fall and Spring semesters.

Professional Development

Students are encouraged to participate in professional development opportunities, including conferences, seminars, and workshops. Through the annual Training and Career Goals Progress Report, students should discuss their professional development activities with their Mentors. Opportunities will be circulated regularly from Tufts CTSI, Tufts Institute for Clinical Research and Health Policy Science (ICRHPS), Tufts Medical Center, Tufts University School of Medicine, and Tufts University Cummings School of Veterinary Medicine. Many of the workshops provided by Tufts CTSI can be completed online through I LEARN (<https://ilearn.tuftsctsi.org/>).

Peer Tutoring Program

A peer tutoring program is available to support students who are seeking extra help in their program coursework or thesis research. Students are eligible to receive up to 10 hours of peer tutoring per semester. Peer tutors are matched to eligible students by the Program Directors, and arrange meetings at mutually convenient times outside of scheduled coursework. The availability of tutoring in the desired topic area is not guaranteed, as it's dependent on the interest and availability of tutors. Students who wish to receive peer tutoring may apply to the CTS Graduate Program Directors. Students may also be referred to the Program Directors by faculty.

Second year MS students or PhD candidates are eligible to apply for paid positions as peer tutors in the CTS Graduate Program. Interested students should apply to the CTS Program Directors with a brief paragraph outlining their interests in serving as tutors, and any relevant teaching experience. Students who have performed well in the CTS program core courses and possess strong oral communication skills will be most attractive candidates as peer tutors.

VIDEO CONFERENCING

Primarily, Video Conferencing is available for the CTS students who are associated with the CTSI affiliates geographically distant from Tufts University Boston Campus. Video Conferencing is also offered to the program's international students.

In addition, if possible, the CTS Graduate Program will support Video Conferencing for all on-campus students who are unable to physically attend class due to illness, conference registrations, meeting commitments, etc. The student is responsible to inform their course director/s and follow the steps below:

1. In advance, a student communicates his/her request via email to Nina Bonnoyer and the course instructor(s).
2. If approved by the course instructor(s), the student receives an email from Nina with hardware requirements (camera, headset, and microphone) and Zoom instructions.
3. Prior to the class/es, the student tests and confirms with Nina the success or if additional assistance is required.

During the class, if there is a technical problem with the connection, students should contact Tufts University IT Support at 617-636-0931 or Nina at 617-636-4927.

IMPORTANT DEADLINES AND EVENTS

The CTS Graduate Program calendars are listed below. Please refer to the Graduate School of Biomedical Sciences Academic Calendar for additional key deadlines and events (<https://GSBS.tufts.edu/studentLife>).

Certificate Program

Date	Responsibility	Information/Contact
June	Summer Registration	Registrar's Office, 6-6767
August	Fall Semester Registration	Registrar's Office, 6-6767
September	Select a Project Mentor	
Fall	Identify a Certificate project and discuss research timeline	With Project Mentor
November	Spring Semester Registration	Registrar's Office, 6-6767
March/April	Discuss and prepare for project completion	With Project Mentor
April 15	Poster Title due for CTS Graduate Program Annual Symposium	To Education Coordinator by noon
May 6, 13, or 20	23rd Annual Graduate program Symposium – poster presentation	Atrium Lobby and Wolff Auditorium or MedEd 114

First Year MS Program

Date	Responsibility	Information/Contact
June	Summer Registration	Registrar's Office, 6-6767
August	Fall Semester Registration	Registrar's Office, 6-6767
September	Statistical Mentor assigned	Delivered by Graduate Program leadership
September	Identify Program & Project Mentors	Graduate Program leadership & training programs
Fall	Confirm a thesis project and research timeline	All Mentors
November	Spring Semester Registration	Registrar's Office, 6-6767
November/ December	Selection of Thesis Chair (must have GSBS faculty appointment)	
November/ December	Thesis Committee Meeting	All Mentors
January 3	TAC Evaluation Form and Training and Career Goals Progress Report due	To Education Coordinator or Program Manager by noon
March 30 *	Thesis Committee Meeting & First draft of Thesis Proposal due to Thesis Committee	All Mentors
April	Summer & Fall Registration	Registrar's Office, 6-6767
April or May	Review for approval of Thesis Proposal	Advisory Committee Meeting
April 13	Final Thesis Proposal with signed TAC Evaluation Form due	To Education Coordinator or Program Manager by noon
April 15	Poster title due for CTS Annual Graduate Program Symposium	To Education Coordinator by noon
May 6, 13, or 20	23rd Annual Graduate Program Symposium- poster presentation	Atrium Lobby and Wolff Auditorium or MedEd 114

*Suggested date

IMPORTANT DEADLINES AND EVENTS

Second Year MS Program

	Date	Responsibility	Information/Contact
	August	Fall Term Registration	Registrar's Office, 6-6767
	November	Spring Term Registration	Registrar's Office, 6-6767
	November 10	TAC Evaluation Form and Training and Career Goals Progress Report due	To Education Coordinator or Program Manager Committee will review and provide feedback
	November 17	Advisory Committee Meeting	Committee will review and provide feedback
	December	Meeting to go over CTS Thesis & GSBS Thesis requirements	Dr. Rodday and Associate Dean Dan Volchok
	January 3*	First Draft to Thesis Committee	Thesis Committee
WAVE 1	January 14*	Final Thesis Draft to Thesis Committee	Thesis Committee
	Feb 1*	Feedback from Thesis Committee	Thesis Committee
	Feb 15*	Final Thesis to Thesis Committee	Thesis Committee
	March 2	Final Thesis with signed Coversheet due	To Education Coordinator or Program Manager by noon
	March 9	Thesis Defense at Advisory Committee Meeting	Committee will review and provide feedback
WAVE 2	January 21*	Final Thesis Draft to the Thesis Committee	Thesis Committee
	Feb 7*	Feedback from Thesis Committee	Thesis Committee
	Feb 21*	Final Thesis to Thesis Committee	Thesis Committee
	March 9	Final Thesis with signed Coversheet due	To Education Coordinator or Program Manager by noon
	March 16	Thesis Defense at Advisory Committee Meeting	Committee will review and provide feedback
	March 28	Complete the Master's Thesis Approval Form	Thesis Chair for signature; submit to the GSBS Dean's Office
	March 28	Student Exit Survey	https://GSBS.tufts.edu/studentLife/currentStudents/forms
	March 28	Upload Thesis	https://GSBS.tufts.edu/studentLife/currentStudents/forms
	May 6, 13, or 20	23rd Annual Graduate Program Symposium – Oral Presentation	Atrium Lobby and Wolff Auditorium or MedEd 114
	May 20	GSBS Awards Reception	Jaharis Courtyard
	May 22	Tufts University Graduation	Medford Campus

*Suggested date

IMPORTANT DEADLINES AND EVENTS

PhD Program

Date	Responsibility	Information/Contact
August	Fall Term Registration	Registrar's Office, 6-6767
November	Spring Term Registration	Registrar's Office, 6-6767
November/ December	Thesis Committee Meeting	All Mentors
January 3	TAC Evaluation Form and Training and Career Goals Progress Report due	To Education Coordinator or Program Manager by noon
April	Summer & Fall Registration	Registrar's Office, 6-6767
April 15	CTS Graduate Program Symposium Poster title submission	To Education Coordinator by noon
April/May	Thesis Committee Meeting	All Mentors
May 6, 13, or 20	23rd Annual Graduate Program Symposium – Poster Presentation or Oral Thesis Presentation for graduates	Atrium Lobby and Wolff Auditorium or MedEd 114
May 20	GSBS Awards Reception	Jaharis Courtyard
May 22	Tufts University Graduation	Medford Campus
May 28	TAC Evaluation Form due	To Education Coordinator or Program Manager by noon

Please refer to the GSBS Calendar for PhD Thesis Defense deadline information.