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The Master of Science in Translational Research (MSTR) is housed within the Institute for Translational Medicine and Therapeutics (ITMAT). The core missions of this institute are (i) to provide an intellectual home and core critical mass for those who pursue translational research; (ii) to expand the number of faculty pursuing translational research at Penn through direct recruitment and enhancement of recruitment packages of any academic entity; (iii) to expand this critical mass by educating trainees and faculty in translational research; and (iv) to become a unified point of contact for Penn investigators seeking information and support to pursue translational research as well as for outside agencies wishing to engage with Penn in this area. The primary educational vehicle to achieve this goal is the MSTR program.

The rationale for the development of this program was to improve the spectrum and quality of research training by providing an educational curriculum to teach the fundamental skills needed to perform translational research.

The University of Pennsylvania is committed to both maintaining the highest standards when training pre and postdoctoral students and providing a program sufficient to ensure that, when completed, the trainee can function independently as a scientific professional. The responsible institutional official for research training is Jonathan Epstein, MD. He has designated the oversight for all the Perelman School of Medicine Masters Programs to the PSOM Office of Master's and Certificate Programs. The daily operations of the MSTR program are the responsibility of the ITMAT education administrative support staff under the direction of the Program Director, Emma Meagher, MD.

Program Objectives

The primary objective is to produce a cadre of highly trained and sophisticated investigators adept in the skills necessary for the translational investigator; to prepare students for an academic career and to position them for future careers as successful academic researchers who will become leaders in their field of research interest.

Program Goals

The program is designed to meet these objectives through the provision of didactic in-depth course work, a professional development core, a formal mentorship program, formal (wet or dry) laboratory training, and specific ongoing guidance with hands-on exposure to protocol and grant development. Individuals in this program are provided with the expertise and methods to attain their goals through learning the basic components of scientific training, the specific methods associated with their translational research interest, as well as training in biomedical research ethics and good clinical practice. MSTR students learn how to independently formulate meaningful hypotheses, design and conduct interpretable experiments, adhere to good laboratory and clinical practices, analyze results, critically understand the broad significance of their research findings, and uphold the highest ethical standards in research. The development of additional skills - including
oral and written communication, grant writing, and laboratory management –are considered integral to a career as a translational investigator.

Upon successful completion of the MSTR program graduates are expected to have developed a strong foundation in the fundamental techniques of translational research. They should be able to apply contemporary research tools to clinically relevant areas of investigation. The MSTR program will produce investigators who are competitive in seeking research support and who are knowledgeable about the complex issues associated with conducting sound translational research. The MSTR program will also assist in the promotion of translational research as a discipline within the Penn community.

**Professional Development Core**

In 2016, ITMAT Education instituted the Professional Development Core (PDC) to support clinical and translational scientists to successfully execute research endeavors on the path to independence. Sessions provide knowledge, skills, and attitudes in key competency areas to enhance translational investigators’ abilities to collaborate, lead, direct, network, manage up, navigate conflicts, negotiate, and more.

**Mentoring Program**

Effective mentoring is a critical component of research training. It facilitates the development of the trainee and conversion into becoming an independent investigator. Mentoring requires that the primary mentor dedicate substantial time to ensure personal and professional development. The MSTR program recognizes that a good mentor builds a relationship with the trainee that is characterized by mutual respect and understanding.

**Thesis**

Trainees are required to engage in a research project of their own design under the supervision of their primary mentor. The primary mentor will also play a role in helping the student identify a feasible research question for the thesis. The thesis should consolidate the students’ knowledge of the principles and practice of translational research, and provide their first experience in writing a comprehensive NIH grant style proposal.
Master of Science in Translational Research Degree Requirements

The MSTR degree is composed of 12 course units

6 core courses (6 c.u.)

1. MTR 600 Introductory Biostatistics
2. MTR 601 Scientific Writing I - Review Writing
3. MTR 602 Proposal Development
4. MTR 603 Disease Measurement
5. MTR 604 Scientific and Ethical Conduct
6. MTR 605 Scientific Writing II – Manuscript Writing

2 elective courses (2 c.u.)

2 laboratory rotations (2 c.u.)

2 thesis credits (2 c.u.)

Description of Required Course Work

MTR 600 Introductory Biostatistics: 1 c.u. (Fall session - year one)

This course approaches statistics from an applied as well as theoretical point of view. Students learn the correct application and interpretation of basic statistical concepts and techniques. The course covers probability estimation, hypothesis testing, nonparametric tests, tests for categorical data, correlation, and regression. Students will be provided with an understanding of statistical methods, skills in the use of software to apply those methods and the critical thinking to interpret analytic results produced by your effort and/or that of fellow researchers.

MTR 601 Scientific Writing I - Review Writing: 1 c.u. (Summer II session - year one)

This course leads students through the process of writing a Review Article during their first summer within the MSTR program. Review articles will be authored with the student’s primary mentor and will be used to accomplish the following goals: 1) Attain rapid familiarity with background in their new area of study; 2) a mechanism for mentor and student to create a productive working/writing relationship; 3) help the student identify key gaps in the literature and/or areas of controversy that would benefit from pivotal experiments; 4) understand the factors that contribute to variability in research outcomes in their area and; 5) introduce the student to other scientists in their new area through an initial publication early in their career. Mentors will be asked to agree to participate in this process, or identify another senior individual in their group who would perform the function as a condition to have MSTR students funded in their program. The course director and members of the curriculum committee will provide guidance and critical reviews throughout the process.
MTR 602 Proposal Development: 1 c.u. (Summer II semester - year one)

Content includes study design and proposal development as they relate to the studies that probe the mechanism of disease and the study of complex traits. It discusses concepts such as writing a background section, asking a research question, designing a study, use of biomarkers, writing a research proposal and addressing feasibility issues. Early development of the research proposal starts during this course and concludes with each student submitting and presenting their proposal to MSTR faculty for critique and feedback.

MTR 603 Disease Measurement: 1 c.u. (Fall semester - year one)

Acquire the knowledge to rationally and effectively incorporate disease measurements, including emerging technologies, into the design of translational and clinical research protocols. Gain a basic understanding of measurement methodologies used in clinical medicine. Understand how "normal" values are determined, and how to interpret test results in the context of patients/research subjects. Approach disease measurements (tests) as a mean of answering questions, and to be able to choose appropriate tests to answer the questions being posed. The measurement aspects of the students’ research protocol are written and evaluated during this course. This course is separated into lab and imaging sections.

MTR 604 Scientific and Ethical Conduct: 1 c.u. (Spring semester - year one)

Students will learn the foundational principles of scientific and ethical conduct of research, complete directed experience in evaluating these principles through IRB membership and ultimately be able to apply them to their own work. By the end of the foundational class sessions, students will understand scientific conduct, ethical considerations including human subjects and animal protections, regulations governing the use of health information, drugs, and devices, good laboratory practices, conflict of interest, and ethics in challenging new research domains. The directed experience will include membership for six months on an Institutional Review Board (IRB) at either Penn or CHOP. This membership experience will expose students to real issues, considerations, and solutions in human subject’s research and study design.

MTR 605 Scientific Writing II - Manuscript Writing: 1 c.u. (Summer I session – year two)

Students will write a primary data manuscript for publication with their primary lab mentor. Emphasis will be placed on identifying publishable data that was either generated by the student, or which is made available to the student for analysis from the mentor’s lab (e.g. perform a new analysis across data from multiple studies, organize and analyze data that is ‘laying in wait’ for someone to publish it). The student will be expected to learn the role of first author including 1) coordination with the senior mentor to write the introduction, 2) organize data, analyses and figures; 3) obtain or write methods and results from collaborators; 4) writing a discussion and; 5) “getting it out the door”. The authorship for the publication is left to the discretion of the mentor in consultation with the originator of the data and the MSTR student. This will both teach the student the value of publishing as an integral part of academic life, and will facilitate their success with subsequent grant applications. The course director will provide guidance and critical review of work throughout the process. Mentors will be asked to agree to participate in this process, or identify another senior individual in their group who would perform the function.
MTR 607 & 608 Thesis: 2 c.u.

Registration for the thesis units represents that the student has completed the fundamentals of the program. Students are expected to complete and defend a research thesis. The thesis project is described in detail in a later section. Evidence of hands-on experience in formulating one or more research questions; searching the medical literature; translating research question(s) into an appropriate research design; assessing study feasibility; writing a detailed study protocol; designing data collection instruments; and implementation of the research protocol.

Completion of the thesis units should reflect all of the above in addition to performance of data analysis. Overall completion should 1) represent the student’s knowledge of the principles and practice of translational research; 2) provide evidence of their first experience in writing a comprehensive NIH grant style proposal; 3) provide documentation of the development, implementation and analysis of the data collected from the research project and; 4) present a summary of the results in 1-2 publishable manuscripts melded into the form of a thesis to defend at a public seminar.

MTR 999 Laboratory Rotations: 2 c.u. (flexible timing)

Completion of two lab rotations are required. Examples of lab rotations include, but are not limited to, a traditional wet bench experience to learn how to develop / perform an assay or measurement technique; a clinical lab rotation learning how to perform / analyze a technique in your specialty; a rotation in a bioinformatics laboratory or a rotation in an imaging laboratory. The lab experiences are selected based on the student’s proposed project and targeted to his/her overall research aims. See the Registration section for information on how to develop and register for a lab.

Internship Program: The MSTR program, in collaboration with its corporate partners, will provide an opportunity for interested students to learn about translational medicine in a Pharmaceutical Industry Internship. The internship will include approximately 10 hours per week for one semester (10 weeks). Internships may span across every facet of the pharmaceutical industry, including discovery, development, regulatory affairs and commercialization. Students will gain hands on experience "translating technology" and will receive independent study credit for the internship. This program will foster greater interactions between industry and academia by exposing MSTR students to the roles they can play in the pharmaceutical industry as a potential career path. Students will be expected to work on site at the corporate partner’s location for 1 day per week, with additional time dedicated to background research and preparation. The internship will be considered equivalent to one laboratory credit (MTR 999).

Internship evaluation process: Students will have both a university and corporate mentor that will participate in training and evaluation. Corporate mentors will be assigned based on the specific content and department in which the internship is performed. Mentors will work together to ensure that interns are meeting the goals and expectations of the internship. Contact Nalaka Gooneratne for more information.
Description of Elective Course Work

In addition to the required courses, students must enroll in two electives that total two course units. These must be graduate level courses in an area of concentration that complements the student’s future career plans in translational research. The student’s primary mentor and the MSTR Programmatic Mentor must approve of the elective courses chosen by the student at least two months prior to course registration. If approved by the Mentoring Committee, the student must contact the course instructor to request permission to enroll in the elective. Once the instructor grants permission then the student must notify the MSTR administrative office who will request that a “permit” be entered into SRS to complete the elective registration. Elective courses outside the Perelman School of Medicine are considered but require prior approval by the program director.

MTR 660 Independent Study: 1 c.u.

MSTR students may perform an independent study for credit based on meeting specific educational requirements. All independent study courses require a designated MSTR independent study supervisor and prior approval from at least one member of the curriculum committee, who will serve as course director for the class. All members of the MSTR curriculum committee are eligible to be MTR 660 course directors. MSTR Independent study courses can be performed in a broad range of activities and settings, as long as the mission and content of the class are consistent with the overarching goals of the MSTR and similar material is not available as an existing class. Independent study plans must have a learning objective, plan of study and methods of assessment. These elements should be drafted by the student and must be approved by both the MSTR designated course director and content specific independent study mentor at least 6 weeks prior to the planned start date. Independent study plans are expected to consist of approximately 10 hrs per week of activities for 10 weeks and may take place in any semester throughout the academic year.

An Example of a Plan of Study

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An essential component of the MSTR degree program is the mentoring program. As previously stated, effective mentoring is critical not only for research training but also to allow the trainee to develop into an independent investigator. Mentoring requires that the primary mentor dedicate substantial time to ensure personal and professional development. A good mentor builds a relationship with the trainee that is characterized by mutual respect and understanding. Attributes of a good mentor include being approachable, available, and willing to share his/her knowledge; listening effectively; providing encouragement and constructive criticism; and offering expertise and guidance. We recognize the importance of these attributes and the significant time required to mentor effectively. For this reason, we have in place the MSTR mentoring program.

The program requires the establishment of specific milestones and the definition as to when these milestones should be accomplished within the training period. Examples of such milestones are 1) data acquisition and analysis; 2) preparation and submission of manuscript(s); 3) grant submission; 4) conditions regarding authorship; 5) mentor expectations of the mentee and; 6) mentee expectations of the mentor.

**The Mentoring Committee**

All students enrolled in the MSTR degree program have a Mentoring Committee. This is composed of the primary mentor and a programmatic mentor. The student may elect to have a secondary mentor(s) to be part of the committee. This mentoring committee functions as an ongoing monitoring group for the student’s progress. Its members are faculty with expertise relevant to both the basic and clinical aspects of the student’s research, and each is expected to contribute their expertise to fostering the student’s research progress.

The primary mentor typically provides the direction for the research project and basic science components of training. They will also guide and instruct the student through the science writing and grantsmanship courses and towards independence and self-sufficiency in publication and in funding. The programmatic mentor supports the overall progress of the student through the MSTR program for both the completion of the curricular elements as well as the research project. Students may need additional support, such as a biostatistics or bioinformatics mentor to provide guidance in the development of the analysis plan at study inception and during the data analysis period in manuscript and thesis development. If possible, students should identify a resource within their professional network.

The student identifies the primary mentor prior to enrollment. The programmatic mentor is assigned to the student by the program director. The mentorship committee meets with the student at the commencement of the program, at the end of year one, and in advance of the thesis defense. The primary mentor is expected to discuss the mentoring compact with the student and set expectations at the beginning of the program, and meet with the student on a weekly to biweekly basis. Additionally, the student meets with the programmatic mentor at the end of the fall semester of the first year and second year to ensure ongoing progress through the program. Additional *ad hoc* meetings may occur as required. The mentoring committee will hold a pre-graduation meeting two to four months prior to the student’s thesis defense.
Translational research training is an integral component in the preparation of physician-scientists for career advancement as scientific professionals. The MSTR trainee will undertake scholarship and research that together provide a training experience essential for career advancement in the science of translational research. The training component is conducted in an apprenticeship model where the trainee works under the supervision of an investigator who is qualified to fulfill the responsibilities of a mentor.

Students are required to engage in a research project of their own design under the supervision of the primary mentor. At the time of application, each student specifies the project they will pursue, along with the primary mentor who will advise and support the clinical research project. Students will use class material and homework assignments to assist in protocol development.

The research should be translational in nature and involve direct measurements on patient-derived samples or the use of innovative therapeutic or diagnostic techniques with laboratory-based elements. There should be demonstrable clinical relevance. The protocol is to be designed by the student under the direct supervision of the mentor. Where appropriate, dual mentorship should be considered; including a basic scientist expert in the technology being used and a clinical investigator expert in the condition being studied. The primary protocol should account for at least 75-80% of the student’s commitment to the program.

Trainees are required to complete a thesis that involves designing a research project, writing a formal research proposal, performing the study described in it, preparing 1-2 comprehensive scholarly scientific paper(s) reporting the results, and presenting and defending the thesis at a public seminar. The defense portion of the seminar will be a formal oral defense of the thesis with three examiners.

The thesis should consolidate students’ knowledge of the principles and practice of translational research, and provide their first experience in writing a comprehensive NIH grant style proposal. Students are expected to develop, implement, and analyze the data collected from the research project and summarize the results in a publishable manuscript(s). The thesis provides hands-on experience in formulating one or more research questions; searching the medical literature; translating research question(s) into an appropriate research design; assessing study feasibility; writing a detailed study protocol; designing data collection instruments; conducting the research, performing data analysis, where appropriate; and preparing a manuscript for publication. The MSTR program requires that a student obtain experience in each of these facets of research. The structure of the proposal is expected to follow the NIH-R01 PHS-398 format as much as possible. Refer to the NIH website link: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.400-phs-398-research-plan-form.htm#Intro

Types of Acceptable Thesis Projects

The key criterion for an acceptable thesis is that it be of publishable quality and magnitude. Feasibility and scientific merit are two major factors to consider when deliberating thesis options. In general, it should be possible to complete the study during the two years of the program.
The thesis project must be able to stand on its own. In particular, the study must have a sufficient sample size to answer a research question. “Pilot” studies are generally not acceptable, but preliminary work that may lead to a larger effort in the future is encouraged, provided the work has adequate scientific merit and statistical power on its own accord. If a study is too small or not adequately designed to answer a question definitively, it will not be publishable in its own right. The student’s primary mentor and advisors can provide substantial guidance in the pursuit of an appropriate question for the thesis proposal. The student is encouraged to think big by outlining a set of steps towards the answer to an important clinical issue and then develop one of the initial steps into a thesis project and proposal.

**Starting the Thesis “from scratch”**

Students will begin the design process for their projects upon entering the program by considering a range of options for addressing research questions of interest. The initial process is focused on finding and refining a relevant clinical question(s) suitable and appropriate to answer with a research study, which is generally considered to be the specific aim(s) of their project. The coursework introduces the principles of scientific study design early in the curriculum to provide the structural underpinning of the students’ discussions with their advisors. In refining the question, students have often changed their research focus as they realize the potential problems and possibilities available to answer questions that they find compelling. Research that has been initiated prior to starting the program will not be acceptable as a thesis. If the research questions have been defined but the protocol is not fully developed and can be modified throughout the year in response to input from all of the resources available to the student in the MSTR program, it is likely that an acceptable project can be designed. The project should be of the student’s own choosing and related to their research and clinical interests. Many students will have engaged in research before entering the program, and continuity with prior research activities is expected and encouraged. It is essential for each student to take advantage of the coursework and meetings with their advisors in developing the research plan in order to ensure that the thesis provides the opportunity for academic growth.

The assessment of having met the criteria for successful defense and completion of the program are based on the examiners being able to say the candidate

1. Understands the concept of translational research and how to set up a rationale for their research question.
2. Understands how to pose and address testable hypotheses.
3. Has an ability to analyze his/her own data and appropriately interpret the results.
4. Appreciates where his/her own data fits in respect to the scientific field in general and the potential of clinical application.
5. Has an appropriate understanding of the value of his/her results to the field and how they may shape future research questions.
6. Successfully provides a clear, logical exposition of the project both in writing and during the oral defense.
7. Answers questions posed by the committee satisfactorily.
Role of the Primary Mentor in the Master’s Thesis

The primary mentor’s role is to help the student identify a feasible research question; explore alternative approaches to answering the question; identify content experts to supplement the mentor’s expertise; and advise the student on protocol development, implementation, analysis, and summary for publication. The mentor’s role is not to assign a thesis to the student, but rather, the mentor should help the student translate his or her own ideas into a research project. Finally, the mentor is responsible for ensuring that the student formulates and adheres to a timeline to complete the thesis.

Role of the Thesis Committee in the Master’s Thesis

Students are required to form a thesis committee, approved by their primary research and program mentor prior to MSTR program orientation. The committee consists of three faculty who are experts in the research area, but have no direct influence on a students’ project. They should be the students’ department chair or division chief or a research, lab, or program mentor. The thesis committee members will provide feedback on the students’ research proposal from inception, attend the proposal presentation and complete an evaluation of the presentation, provide additional feedback on the project throughout the MSTR program, and will ultimately serve as a reviewer for the thesis defense.

Students will need to manage the committee engagement and scheduling of meetings with their thesis advisors. Students should establish the frequency of meetings based on research progress and/or road blocks that require input for critical decision points. If a committee member becomes a lab mentor or otherwise involved in the project, an additional faculty member will be needed for the thesis defense. If this arrangement is necessary, inform the MSTR administrative office.

Laboratory Research for MSTR Students

Students are required to participate in primary laboratory research that provides a meaningful experience in translational research. Students are expected to formulate a lab proposal, conduct the research in the laboratory, collect data, and analyze it. The purpose of the lab experience is to emphasize the basic components of the translational research experience, to appreciate that the underpinnings of translational research is understanding disease mechanism, and to learn the subtleties of measurement of disease process and the complexity this brings to the area of human research.

MTR 999 Laboratory Units

MSTR degree candidates are required to complete two lab rotations of primary, meaningful laboratory research in a translational research setting. Successful completion of each lab rotation results in the awarding of one credit unit. The purpose of the lab rotation is to emphasize the basic components of the translational research experience, to appreciate that the underpinnings of translational research is understanding disease mechanism, and to learn the subtleties of the measurement of disease process and the complexity this brings to the area of human research.
The student formulates a lab proposal, conducts the research in the laboratory, collects data, and analyzes it. Each lab rotation is meant to provide experience working in a new environment or learning a new technique. Examples of lab units include, but are not limited to:

- a traditional wet bench experience to learn how to develop an assay
- a clinical lab rotation learning how to perform and analyze a technique in your specialty
- a rotation in a bioinformatics laboratory
- a rotation in an imaging laboratory.

Process and Registration

Students need to identify a lab mentor who will oversee the lab rotation. The lab mentor and the program mentor must approve the lab proposal prior to registering for a MTR 999 Unit. To get approval, students should complete the lab proposal form found on the MSTR Canvas webpage, obtain the lab mentor’s approval and signature on the form, and then forward the signed form to their program mentor for their final approval. Once approved, students will be registered for the MTR 999 unit by the MSTR Administrative Office. The Lab Rotation approval must be received prior to commencing the lab rotation.

*MTR 999 Lab course units will not be registered without an approved proposal.*

Expectations

During the lab, students are required to document their experiments in a laboratory notebook in accordance with the guidelines established in their research laboratory. The complete laboratory notebook ensures research integrity, intellectual property protection and the ability for anyone to recreate the experiment in its entirety.

A short NIH webinar on keeping a lab notebook can be found here: [https://www.training.nih.gov/oite-yt/keepingalaboratorynotebook](https://www.training.nih.gov/oite-yt/keepingalaboratorynotebook).

Lab Report and Grading

At the end of the lab, students are required to write a 1-3 page report by completing the MTR 999 Lab Report Template (found on the MSTR Canvas webpage) that outlines the:

- Purpose of the lab/Background
- Methods
- Results
- Discussion

The quality of the written report should be sufficient for incorporation into the MSTR thesis or a publication submission. The lab grade awarded is a composite assessment of the student’s lab mentor evaluation of the rotation and the program mentor’s evaluation of the final report.
MTR 999 Lab courses will not receive a grade until lab reports are submitted and approved. It is the responsibility of the student to submit the report in a timely fashion after completion of the rotation. The maximum time for completion is the grading deadline for the next term (i.e. a lab report for a lab unit registered in fall term is due no later than at the end of the following spring term.)

Process Overview:

**Student Proposes Lab**
- Student completes lab proposal form
- Lab Mentor approves & signs proposal
- Program Mentor approves by signing off on proposal
- Student submits approved proposal to MSTR Administrative Office
- MSTR Administrative Office registers student

**Student Conducts Research in Lab**
- Lab work is to be conducted by the student
- Student should maintain laboratory records/notebook in accordance with their lab

**Student Completes Lab**
- Student submits lab report
- Purpose/Background
- Methods
- Results
- Discussion
- Program Mentor and Lab Mentor review and sign off on report
- Lab Mentor submits grade to MSTR Administrative Office

**Conduct of the Research**

It is common that the student personally conduct all aspects of the thesis project. In circumstances where the amount of work required exceeds what could be reasonably expected of a single investigator, it is appropriate to work with additional researchers in the collection of data and data entry. In such cases, the student is expected to oversee the process and provide sufficient monitoring to ensure that the quality of the data is not compromised. Once the data is collected and properly entered into a computer database, the student is responsible for data cleaning, creating analytic files, and the primary analysis of the data. It is expected that the student will seek the advice of his or her mentors during this process to ensure an efficient and appropriate analysis process.

**The Final Product**

The writing of the thesis is again, the primary responsibility of the student, with input from his/her mentors including reading and comments on the paper as the process progresses. The final thesis should be in the format of a journal article and should be acceptable for submission to a journal.
When the final thesis is near complete, the student must notify the MSTR administration office of their plans to defend. The primary mentor should review the thesis first. Once the mentor’s suggestions are incorporated, the thesis must be submitted to the other members of the Mentoring Committee for formal approval. Once the student responds satisfactorily to the comments of all committee members, final approval of the thesis will be conveyed to the MSTR Program Office from the primary and program mentors by completion of the thesis review form. The student will send an electronic copy of the thesis to the MSTR Program Office for distribution to the examining committee. The examiners will be given an opportunity to express any major flaws that may prevent the student from passing on the day of the defense.

It is expected that all MSTR theses will be submitted for publication and a copy of the final paper should be submitted to the MTR Program Office to be included in the student’s file.

For publications, students should refer to the ‘Citing ITMAT Education Funding Awards’ page on the MSTR program website to identify if it is required to acknowledge grant support. [http://www.itmat.upenn.edu/Citing_ITMATEd_Funding.html](http://www.itmat.upenn.edu/Citing_ITMATEd_Funding.html)

**Procedures for Changing the Thesis**

All students in the Master of Science in Translational Research (MSTR) program must develop and complete a thesis project as fulfillment for the degree. This process involves developing a project under the guidance of the student’s mentor, receiving feedback from fellow students and faculty, executing the project, and writing up the thesis for approval by the Mentoring Committee.

It is very important to note that changes to the originally proposed thesis project should be extremely rare. The originally proposed thesis project will have been developed with careful guidance from the student’s mentor and numerous other faculty and students. As such, the project should be tenable from both a scientific and logistic standpoint. It is only under extremely rare circumstances that a thesis project should need to be changed. Nonetheless, it is recognized that the initially proposed thesis may not always be tenable for reasons of logistics, time, or unforeseeable circumstances. Should it become impossible to complete the originally designed thesis, a student may request to change the project.

The following steps must be taken prior to changing the originally approved thesis topic:

1) The reason for not completing the originally proposed project must be documented in writing and distributed to the student’s primary mentor, the programmatic mentor, and the MSTR Program Director.
2) The above-mentioned faculty members must all agree that the thesis project is not feasible.
3) The student must then propose an alternate thesis project to their primary mentor, programmatic mentor and Program Director of the MSTR program. This project must meet the same requirements as the originally proposed thesis, including writing of a formal protocol under the guidance of the student’s mentor (even if the project has already been started), approval of the protocol by the Program Director and mentoring committee, and proper execution and completion of the project.
It is recognized that students will often be working on numerous projects along with their originally proposed thesis project. One of these projects may be used as the student’s thesis project only if the project was developed under the guidance of the student’s mentor. Projects developed with other faculty members, or developed prior to enrolling in the Master’s program, will not qualify for the Master’s thesis. Regardless, all of the above-mentioned steps must be taken before the project is acceptable as a thesis.
Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure. At the MSTR graduate level, the grade of C, while passing, does not constitute satisfactory performance. Letter grades may be modified by a plus (+) or minus (-) sign at the discretion of the course director. The minimum standard for satisfactory work in each course is a B-. The MSTR degree program additionally requires that the quality of the students work and their conduct in the program is of an appropriate professional quality to ensure advancement. Failure to meet these requirements may result in a student being placed on probation and/or require a student to withdraw despite a satisfactory grade average.

The mark of I is used to designate “incomplete.” A student who fails to complete a course and does not withdraw or change his/her status to auditor within the prescribed period shall receive at the instructor's discretion either a grade of I (incomplete) or F (failure). It is expected, in general, that a student shall complete the work of a course during the term in which that course is taken. The instructor may permit an extension of time up to one year for the completion of the course. In such cases, any course which is still incomplete after one calendar year from its official ending must remain as “incomplete” on the student's record and shall not be credited toward a degree.

For Lab (MTR 999) and Thesis Credits (MTR 607, 608) students who have not completed requirements for a grade at the completion of the registered term will receive the mark of Not Graded (GR) on their transcript. For lab credits, this GR status should be resolved by submission of lab report and grade form by the end of the next grading term or in advance of the pre-graduation meeting, whichever comes first. For Thesis Credits, the GR will remain until successful written thesis and oral defense. Students have five years from matriculation to complete the thesis defense.

Academic Standing

The MSTR degree program has specific academic standards that are expected of all students. If a student fails to obtain a passing grade for a required course they will be placed on academic probation. Students may continue to enroll in other courses while on probation with the permission of the MSTR Program Director and input from the course director, as needed. The student must make arrangements with the course director to remediate any grades lower than a B- and these arrangements must be approved by the program director with input from the MSTR Advisory Committee as needed.

A remediation will be required that may include one of the following: retake an end of course exam, submit a written assignment as designed by the course instructor, or take another course. This will be at the discretion of the instructor for that course. The grade as entered in SRS may not be changed. Additional remediation may be required based on the judgment of the program director, the student's advisor, the MSTR Advisory Committee, and/or the course directors. Any student who...
receives an unacceptable grade in a course for the second time or fails to meet the remediation plan will be dismissed and will not be eligible for re-admission. The status of any student who is or has previously been on probation and who receives an unacceptable grade for an additional course will be reviewed by the MSTR Advisory Committee, the program director, and the student's mentoring committee. The committee is authorized to dismiss the student or allow the student to remain in the program on a probationary status.

Any student who exhibits unprofessional behavior as determined by the programmatic leadership will be evaluated for probation. Continued unprofessional behavior will be grounds for removal from the program and withdrawal of all associated financial support.

**Academic Grievances**

Students who have a concern about a matter related to the MSTR program, whether it concerns a course, instructor, or mentorship, are encouraged to come to the MSTR Program Office (8032 Maloney Bldg, HUP) to discuss their concern. Alternatively, the student may wish to speak directly with their Programmatic Mentor and/or the MSTR Program Director.

**Transfer Credit Policy**

Twelve course units including completion of two thesis credits are required for the MSTR degree. MSTR students may request to transfer credit for graduate level courses completed at other schools within the University or from an accredited program. All transfer of credit requests will be considered on a case by case basis.

Transfer credit may not be applied to the two laboratory course units required for the MSTR degree. Courses taken on a pass/fail basis and courses taken more than three years ago will not be considered for transfer credit. Only courses in which the student received a grade of "B" (3.0) or higher will be considered for transfer credit. No course may be counted toward degree requirements if it has been used toward the requirements for more than one other degree.

Requests for transfer credit should be submitted to the MSTR Program Director together with a course syllabus for the course under consideration. The director will request a review of the course by a MSTR faculty member in that content area for its appropriateness for MSTR transfer credit.

Students may request substitution of a core course with a more advanced course in that content area. The process for substitution is the same as that for transfer credit.

**Audit Policy**

Students who wish to audit a course are expected to designate the audit at the time of registration. Auditing course work is discouraged, as full tuition is charged but no credit is earned toward the MSTR degree. If a student wishes to change a course status from credit to audit, s/he must obtain permission from the course instructor before the “drop/add” period ends. The audited course will appear on the transcript with the grade of “AUD” and no credit will be earned toward graduation. Students are not permitted to change the course status from graded to audit after the course has
Students funded from ITMAT, CTSA KL2 and TL1 awards are not permitted to use these funds to support tuition costs for auditing courses.

Student Conduct

MSTR students must comply with the University's Code of Student Conduct and other University policies related to student conduct that appear in The PennBook: Resources, Policies and Procedures Handbook, available here: [https://catalog.upenn.edu/pennbook/](https://catalog.upenn.edu/pennbook/). These include, but are not limited to, policies on sexual harassment, acquaintance rape and sexual violence, appropriate use of electronic resources, open expression, and drug and alcohol usage. Students are also expected to abide by the BGS policies adopted by MaC including the Authorship Policy when publishing their research and BGS Student Expectations including the Code of Academic Integrity. The PennBook, BGS Policies, and a directory of other important University Policies relevant to Graduate Education are available here: [http://www.med.upenn.edu/bgs/staff.shtml](http://www.med.upenn.edu/bgs/staff.shtml)

Any student who exhibits unprofessional behavior as determined by program leadership will be evaluated for probation. Continued unprofessional behavior will be grounds for removal from the program.

Code of Academic Integrity

The most fundamental value of any academic community is intellectual honesty; accordingly, all academic communities rely upon the integrity of each and every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. Violations of the Code include but are not limited to the following acts:

A. **Cheating:** using or attempting to use unauthorized assistance, material or study aids in examinations or any other academic work, or preventing, or attempting to prevent another from using authorized assistance, material, or study aids. Example: using a cheat sheet in a quiz or exam, altering a graded exam and resubmitting it for a better grade, etc.

B. **Plagiarism:** using the ideas, data or language of another without specific and proper acknowledgment. Example: copying another person's paper, article, or computer work and submitting it for an assignment, cloning someone else's ideas without attribution, failing to use quotation marks where appropriate, etc.

C. **Fabrication:** submitting contrived or altered information in any academic exercise. Example: making up data for an experiment, fudging data, citing nonexistent articles, contriving sources, etc.

D. **Multiple Submission:** submitting, without prior permission, any work submitted to fulfill another academic requirement.

E. **Misrepresentation of Academic Records:** misrepresenting or tampering with or attempting to tamper with any portion of one's own or any other person's transcripts or academic record, either before or after coming to the University of Pennsylvania. Example: forging a change of grade slip, tampering with computer records, falsifying academic information on one's resume, etc.

v. 06/2019
F. *Facilitating Academic Dishonesty*: knowingly helping or attempting to help another violate provisions of this Code. Example: working together on a take-home exam, etc.

G. *Unfair Advantage*: attempting to gain unauthorized advantage over fellow students in an academic exercise. Example: gaining or providing unauthorized access to examination materials, obstructing or interfering with another student’s efforts in an academic exercise, lying about a need for an extension for an exam or paper, continuing to write even when time is up during an exam, destroying or keeping library materials for one’s own use, etc.

Alleged violations of the BGS Code of Academic Integrity are adjudicated in accordance with the Charter of Biomedical Graduate Studies Student Judicial System. Alleged research ethics violations are handled in accordance with the University’s Procedures Regarding Misconduct in Research for Non Faculty Members of the Research Community. If a student is unsure whether his action(s) constitute a violation of the Code of Academic Integrity, then it is that student’s responsibility to consult with the instructor to clarify any ambiguities.

**Time Limitation**

The MSTR program is designed as a full-time program. The time to complete the didactics is typically 2 years and the research project may take up to 3 years to complete. The maximum time permitted to complete the MSTR degree is 5 years from the date of matriculation.

**Registration**

**Continuous Registration**

Continuous registration as a Master’s student is required unless a formal leave of absence is granted by the Program Director. A leave of absence will be granted for military duty, medical reasons, and for family leave; this leave is typically for up to one year and “stops the clock” on time to completion. Personal leave for other reasons may be granted for up to one year with the approval of the Program Director, but it does not automatically change the time limit.

**Registration Process**

The MSTR administrative office is responsible for registering all students for MSTR courses. Students can change their course schedule without penalty during the add/drop period.

*To register for electives*, students must first obtain approval from their MSTR Mentoring Committee then contact the course instructor to request permission to enroll. Once the instructor grants permission, then the student must notify the MSTR administrative office will request a "permit" be entered to complete the elective registration.

*To register for labs*, students must submit the lab proposal to their program mentor. After receiving approval, the proposal and approval must be submitted to the MSTR administrative office by the registration deadline.

*To register for the industry internship*, students must arrange the experience with Nalaka Gooneratne. Approval by Dr. Gooneratne must be sent to the MSTR administrative office.
To register for independent study, students must submit a proposal to their MSTR program mentor. After receiving approval, the proposal and approval must be submitted to the MSTR administrative office before the registration deadline.

Students are strongly encouraged to verify course registration, tuition bills and grades through the student portal: http://pennintouch.apps.upenn.edu

Students may refer to the Penn Three-Year Academic Calendar to find out registration dates and add/drop periods on the Registrar’s website: https://www.registrar.upenn.edu/.

Information on course offerings (e.g. timetables, classrooms, and course descriptions) can also be found on the Registrar's website. For the most up-to-date information on MSTR courses visit the MSTR website at: http://www.itmat.upenn.edu/mstr/.

For specific MSTR registration deadlines, contact the MSTR administrative office.

Leave of Absence

A student who wishes to take a leave of absence must submit a written request to the MSTR Program Office for initial approval and then it will be reviewed by the Associate Dean in the Office of Master's and Certificate Programs for final approval. The granting of a leave of absence does not automatically change the time limit for the degree.
Throughout the program, students will be required to keep track of and follow through on all administrative requirements for the MSTR degree. Below is a summarized list of the requirements:

1) Graduation application – In order to be considered for conferral of the degree students must complete an online graduation application approximately two months prior to the expected conferral date. The graduation application initiates an academic audit that, assuming all requirements are met, places the student with the next graduation cohort. The MSTR degree is conferred by the University of Pennsylvania Perelman School of Medicine and is granted in May, August and December of each year.

2) Course evaluations – students are required to complete an evaluation for every MSTR course. Students will receive an email notification and website link to the online evaluation at the end of each term. Grades will not be released until evaluations are complete.

3) Professional Development Surveys – students are required to complete an online evaluation for each Professional Development session in the MSTR program. Students will receive an email with a survey link from the MSTR administrative office.

4) MSTR Surveys – students are required to complete an online evaluation of the MSTR program each year. You will receive an email with a survey link from the MSTR administrative office. Graduating students are required to complete an exit survey evaluating the program and their mentors. Thesis grades will not be released until the evaluations are complete.

Research Regulations Compliance

Because much of the research conducted by our students involves clinical data, it is essential that all studies comply with various research regulations. These policies are designed to protect patient and human subject privacy.
PennCard

PennCard is the official identification card of the University of Pennsylvania and is required for all students. The PennCard Center is located on the 2nd floor of the Penn Bookstore at 3601 Walnut Street. A valid government issued photo I.D. will be required in order to pick up your new PennCard. The Office can be reached at http://www.upenn.edu/penncard.

PennKey

Your PennKey name and password gives you access to PennNet, a Penn e-mail account, and many other essential services managed through the MSTR Program. All students are required to have a current, active PennKey and password.

Penn InTouch

Penn InTouch provides secure web access to view current billing information, course registration and schedules, academic records, student health insurance, etc. Access to this site requires login with PennKey and password: http://pennintouch.apps.upenn.edu.

The PennPortal

The PennPortal webpage bundles together links to important information for students. Access the PennPortal at www.upenn.edu/penn_portal/.

Canvas

Canvas is the online course site system used for the majority of MSTR courses and by the University. Individual pages are set up for each MSTR Course and can be accessed with PennKey and Password.

Log in at https://canvas.upenn.edu

Support: canvas@pobox.upenn.edu
Description of Fees

The MSTR tuition is calculated based on course unit plus general and technical fees. Tuition for non-MSTR courses vary by department and students should contact the individual department to verify tuition cost.

For current tuition rates, visit [http://www.itmat.upenn.edu/mstr-tuition.html](http://www.itmat.upenn.edu/mstr-tuition.html)

**General Fee:** The amount of the general fee is based on the number of course units taken. The general fee enables the University to maintain essential facilities such as the library system, museums and institutes, special laboratories, the Student Health Service, Athletics, and Career Services, all of which provide benefits to students both before and after graduation.

**Technical Fee:** Students are charged a technical fee for computing services such as access to computer labs and use of email accounts.

**Clinical Fee:** Full-time students are required either to pay a separate Clinical Fee for access to the Student Health Service or to enroll in a health insurance plan that provides a capitated payment to the Student Health Service (i.e., the Penn Student Insurance Plan or a private plan that provides an equivalent capitated payment). A review of the Penn Student Insurance Plan can be found at the following website: [http://www.vpul.upenn.edu/shs/shi.html](http://www.vpul.upenn.edu/shs/shi.html)
CURRICULUM CONCENTRATIONS

Discovery

Discovery is for trainees who are elucidating the basic pathophysiological etiology and/or process of disease. Projects may be proof of concept in cell or animal models or human samples.

Translational Therapeutics and Regulatory Science

Translational Therapeutics and Regulatory Science focuses on testing discoveries for preclinical and/or clinical effects. Projects may be first in humans, phase 1, or assessing the safety, efficacy, quality, and performance of regulated products. There are three main components to this curriculum: a core didactic class in Therapeutics Development (MTR 620); an internship in industry; and a thesis project with a focus in translational therapeutics. The goal of the track is to enhance training in commercialization of academic technology.

Entrepreneurial Science

Entrepreneurial Science offers trainees the opportunity to translate biomedical research into innovative solutions and to develop approaches to commercialization. Graduates of the program are expected to have a more robust entrepreneurial mindset coupled with tangible skills to bring biomedical research to market. The program is designed to support a trainee as they acquire skills in key aspects of: 1) Needs assessment, 2) Idea development, 3) Scientific methodology, and 4) Approaches to commercialization. The program is directed by Nalaka Gooneratne, M.D., M.Sc.

Bioinformatics/Biomedical Informatics

The Bioinformatics/Biomedical Informatics concentration aims to train a new generation of translational scientists in informatics approaches. The rapidly expanding field of biomedical informatics defines how we compare and evaluate healthcare data to both understand and introduce improvements to care (biomedical informatics), as well as the use of healthcare data to conduct discovery-based investigation of biological systems (bioinformatics). Our goal in introducing the biomedical informatics track within the MSTR program is to not only produce translational scientists who are customers and collaborators with informaticians, but to empower these scientists to leverage informatics approaches to develop and test their own hypotheses. The program is directed by Benjamin Voight, PhD.

More information about these concentrations can be found here: http://www.itmat.upenn.edu/mstr-concentrations.html

An appendix will be attached to the end of the student handbook with suggested electives for each concentration.
JOINT DEGREE PROGRAMS

Potential applicants for the joint-degree are Medical, Dental, Veterinary and Nursing students. The following joint-degree programs are offered or are in development in conjunction with MSTR:

(1) MD-MSTR
(2) MSN/PhD-MSTR
(3) VMD-MSTR
(4) DMD-MSTR

Students interested in pursuing a joint degree program are encouraged to discuss their interests with the MSTR Program Director, Emma Meagher, M.D.

MD-MSTR Curriculum and Program Structure

Students will complete three years of the MD curriculum before beginning full time study in the MSTR program in July at the end of year 3. (Students who are interested in the program early in their time as medical students may begin exploring the possibilities for their research project before beginning full time course work.

The July 1 start date for full time MSTR coursework means that MD-MSTR students will have only six months (from January through June) of year 3 to complete step 1 of the boards and take the electives and “Sub-Is” they need for residency application. Faculty advising and close communication with the Registrar, Helene Weinberg about scheduling and finances are absolutely essential given the compressed time frame. Students considering the MD-MSTR program should start planning as early as possible in their first or second year of medical school to make the best use of their time. All of year 4 and the fall of year 5 will be devoted to full time work toward the MSTR degree, during which time students are not registered for the MD. The spring of year 5 will be devoted to completing the final requirements for both degrees.

The MD-MSTR requirements are identical to those of the free-standing MSTR degree option.

6 core courses

1. MTR 600 Introductory Biostatistics
2. MTR 601 Scientific Writing I - Review Writing
3. MTR 602 Proposal Development
4. MTR 603 Disease Measurement
5. MTR 604 Scientific and Ethical Conduct
6. MTR 605 Scientific Writing II - Manuscript Writing

2 elective courses

2 laboratory rotations

2 credits for research project and thesis
The **MSTR Leadership Committee** is charged with: 1) providing career guidance to prospective MD-MSTR students, including MD students who are interested in translational research but are undecided about the MSTR program; 2) providing advice and counseling to students enrolled in the MD-MSTR joint-degree program; and 3) screening applications to the MD-MSTR program and make recommendations to the MSTR admissions committee.

**For more information about MD-MSTR contact:**

- **Emma Meagher**, MD  
  Director, MSTR Program  
  8032 Maloney Bldg. | 215-662-2174  
  emma@upenn.edu

- **Amy Nothelfer**  
  Associate Director, PSOM Combined Degree and Physician Scholar Programs  
  JMEC, 6th Floor, #668 | 215-746-2359  
  nothelfe@pennmedicine.upenn.edu

- **Helene Weinberg**  
  Registrar, PSOM Registrar's Office  
  JMEC, 6th Floor | 215-898-4646  
  hweinber@pennmedicine.upenn.edu

- **Jean Fox**  
  Financial Aid Manager, PSOM Admissions and Financial Aid Office  
  JMEC, 6th Floor | 215-898-9118  
  jmfox@pennmedicine.upenn.edu

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**SAMPLE STUDY PLAN – MD-MSTR**  
(MSTR courses in red)

<table>
<thead>
<tr>
<th>Year</th>
<th>Fall</th>
<th>Spring</th>
<th>Summer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>MD curriculum (Modules 1)</td>
<td>MD curriculum (Modules 2)</td>
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</tr>
<tr>
<td>2</td>
<td>MD curriculum (Modules 2)</td>
<td>MD curriculum (Modules 4)</td>
<td>MD curriculum (Modules 4)</td>
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</table>
| 3    | MD curriculum (Modules 4) | Boards 1 and MD curriculum (Module 5) | MTR 601 (1.0 c.u.)  
MTR 602 (1.0 c.u.)  
(Summer II) |
| 4    | MTR 600 (1.0 c.u.)  
MTR 603 (1.0 c.u.) | MTR 604 (1.0 c.u.)  
Elective 1 (1.0 c.u.) | MTR 605 (1 c.u.)  
MTR 999 (1 c.u.)  
(Summer 1) |
| 5    | MTR 999 (1.0 c.u.)  
Elective 2 (1.0 c.u.) | MD curriculum (Module 5)  
MTR 607 (1.0 c.u.)  
MTR 608 (1.0 c.u.) |        |
DMD-MSTR Curriculum and Program Structure

Students interested in the DMD-MSTR combined degree will apply in the fall of their first year of dental school through the dental school’s combined degree committee in consultation with the Proposal Evaluation Committee. Accepted students will begin coursework for the MSTR program in the Summer following Year 1 of dental school, at which time they will also complete a 4 week intense lab orientation in the laboratory of their chosen mentor. Students will then follow the plan of study outlined in the grid below. After completing all MSTR coursework, students will take a refresher course for the dental school prior to returning to the DMD curriculum for years 4 and 5. Students will also continue their MSTR research resulting in a Thesis Defense in the spring of year 5 of the combined degree program.

This plan of study allows 6 semesters of time dedicated to MSTR coursework.

The DMD-MSTR requirements are as follows:

6 core courses:

1. MTR 600 Introductory Biostatistics
2. MTR 601 Scientific Writing 1 – Review Writing
3. MTR 602 Proposal Development
4. MTR 603 Disease Measurement
5. MTR 604 Scientific and Ethical Conduct
6. MTR 605 Scientific Writing II – Manuscript Writing

2 Elective Courses (Cross-Reference with DMD Curriculum)

1. DMD 520: Microbiology
2. DMD 625: Pharmacology

2 Laboratory rotations

2 credits for research project and thesis
## DMD-MSTR Sample Study Plan

(MSTR courses in red)

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<thead>
<tr>
<th>YEAR</th>
<th>FALL</th>
<th>SPRING</th>
<th>SUMMER</th>
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<td>DMD-Lab Orientation</td>
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<td>DMD curriculum</td>
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<td>Elective 2: DMD 625</td>
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<td>MTR 999 (1.0) – Lab</td>
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<td>3</td>
<td>MTR 600 (1.0)</td>
<td>MTR 604 (1.0)</td>
<td>Summer Session I</td>
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<td>MTR 603 (1.0)</td>
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<td>MTR 605 (1.0)</td>
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<td>DMD curriculum</td>
<td>DMD curriculum</td>
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<td>MTR 607 (1.0)</td>
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<tr>
<td>5</td>
<td>DMD curriculum</td>
<td>DMD curriculum</td>
<td>MSTR Thesis Defense</td>
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**MSTR Thesis Defense**
The institutional governance and oversight of the Master of Science in Translational Research Program resides in the Perelman School of Medicine (PSOM) Office of Master’s and Certificate Programs (MaC) (https://www.med.upenn.edu/psom/masters.html) within the Office of the Vice Dean for Research and Research Training. The Academic home for the MSTR program is the Institute for Translational Medicine and Therapeutics (ITMAT).

The Participating Schools in the MSTR program are the Schools of: Medicine, Veterinary Medicine, Nursing, Bioengineering and Dental Medicine.

The Program Director is responsible for administrative oversight and academic leadership of the program. The Director also serves as a primary academic advisor to MSTR students and is the chairperson of the Advisory Committee and the Selection Committee. The current Program Director is Emma Meagher, MD.

The MSTR Curriculum Committee serves generally to advise the program leadership on all matters related to implementation and evaluation of the MSTR program and other related activities. The curriculum committee is responsible for formal decision-making on academic aspects of the MSTR degree program. The committee is primarily composed of course directors and program mentors who evaluate existing curriculum and implement modifications. Specific responsibilities of this committee include establishing criteria for membership in the MSTR program, monitoring the work of the standing committees, recruiting faculty for the program, and developing liaisons with appropriate Penn centers and institutes.

The MSTR Selection Committee meets to identify new MSTR students and award funding. The selection committee is responsible for reviewing all applications to the degree programs and associated funding mechanisms. The members interview applicants and recommend acceptance on the basis of a uniform set of criteria related to the applicant, project, mentoring, and resources.
Discoveries

For students who are elucidating the basic pathophysiological etiology and/or process of disease. Projects may be proof of concept in cell or animal models or human samples.

Suggested Electives (Choose 2 c.u.):

- MTR 606 Grantsmanship or MTR 623 Writing an NIH Grant
- BIOM555 Regulation of the Genome
  - Genome Maintenance; Transcription; Chromatin Modifications
- CAMB 510 Immunology
  - This course aims to educate CAMB students in the basic principles of including the basic and applied aspects of hematopoiesis, antigen presentation, signalling, mechanisms of innate and adaptive immunity, lymphocyte development, memory, and host protective mechanisms against pathogen infection.
- CAMB 512 Cancer Genetics and Biology
  - The course objective is to introduce the students to important and current concepts in Cancer Biology and Cancer Genetics and it is organized into 4 broad thematic groups: a. Cell-Autonomous Mechanisms (e.g., tumor suppressor and oncogene function, DNA repair pathways, senescence, apoptosis), b. Non Cell-Autonomous Mechanisms (e.g., tumor microenvironment, hypoxia, angiogenesis), c. Organ Systems (e.g., pancreatic cancer, hematopoietic malignancies) and d. Therapeutic Approaches (e.g., protein kinase inhibitors, immunotherapy, radiation therapy).
- CAMB609 VACCINES AND IMMUNE THERAPY: Vaccines and Immune Therapeutics
  - Initial lectures review immune mechanisms believed to be responsible for vaccine induced protection from disease. Subsequent lectures build on this background to explore the science of vaccines for diverse pathogens, including agents of bioterrorism as well as vaccines for cancer. An appreciation for the application of laboratory science to the clinical development and studies of vaccines is provided in the next section of the course along with lectures, which focus on the regulatory, safety, and ethical implications of vaccines in different world situations. The financial implications of specific vaccines on global health is one focus of the course.
- CAMB630 Topics in Human Genetics and Disease
  - Building on the foundations of the Human Genome and HapMap projects, as well as parallel efforts in model organisms, research in human genetics and genomics is progressing rapidly. Our understanding of basic concepts in genetics, and Mendelian and non-Mendelian human genetic disease is proceeding at an unprecedented pace. This course will provide students with an overview to approaches to understanding current problems and techniques in human genetics.
- CAMB632 Cell Control by Signal Transduction Pathways
This course will examine how various signal transduction mechanisms influence cell functions including replication, growth, transcription, translation and intracellular trafficking. The primary signal transduction pathways to be examined include those mediate by Notch, TGF-β, TNF-α, Ras, and Rho. We will also discuss intracellular signaling in response to DNA damage and explore in depth some of the key classes of enzymes involved in transmitting signals including kinases and phosphatases.

• CAMB/GCB 752 Genomics
  o The goals of the course are to 1) introduce the basic principles involved in mapping and sequencing genomes, 2) familiarize the students with new instrumentation, informatics tools, and laboratory automation technologies related to genomics; 3) teach the students how to access the information and biological materials that are being developed in genomics, and 4) examine how these new tools and resources are being applied to specific research.

• BMB 585 Wistar Advanced Cancer Biology Course: Cancer Pathways
  o The course will cover basic pathways and mechanisms of cancer development and progression as well as current approaches for the identification of therapies for the treatment of cancer. The approach is designed to provide students with an integrated learning platform combining up-to-date basic mechanistic understanding of cancer pathways with more translational, disease-relevant topics in cancer therapy and molecular drug discovery.

• PHRM 570 Vascular biology, medicine and engineering
  o Cardiovascular system and blood; Coagulation and platelets; Blood vessels, endothelial function and vasoregulation; Inflammation; Atherosclerosis & vascular pathology; Novel approaches and therapies

• PHRM 580: Topics in Pharmacogenomics
  o This course will survey the emerging technologies and computational advances that have permitted the field of Pharmacogenomics to mature into a major biomedical discipline over the past few years. It will consider the likely impact on disease target identification; the development of new drugs for established and “niche” markets; the advent of “personalized medicine” including the selection of therapies that have maximum efficacy and minimum side-effect profiles. This course will also touch on some of the ethical issues associated with the routine genetic testing of patients to facilitate treatment choices and clinical monitoring.

**Translational Therapeutics and Regulatory Science**

*For students who are testing discoveries for preclinical and/or clinical effect. Projects may be first in humans, phase 1, or assessing the safety, efficacy, quality, and performance of regulated products.*

Suggested Electives (Choose 2 c.u.):

• MTR 606 Grantsmanship or MTR 623 Writing an NIH Grant
• MTR 621 Cell and Gene Therapy
This course will provide students with a general overview of translational research in the area of gene and cell therapy. This would include technical considerations, translating preclinical investigation into therapeutics, the execution of gene and cell therapies clinical trials, and key regulatory issues. Entrepreneurial considerations will be discussed as well. By the end of this course, students will understand the basic technologies employed for gene and cell therapy along with approaches and pitfalls to translating these therapies into clinical applications including regulatory and commercial aspects of this emerging area.

**REG 622 New Trends in Medicine and Vaccine Discovery**

Modern drug discovery has evolved beyond small molecule drugs to include various biological approaches from proteins to cell and gene therapy, which has enabled progress in a variety of fields, including rare diseases, immuno-oncology, precision medicine, and biomarkers. The goal of this course is for students to understand newer treatment modalities and approaches beyond ‘one size fits all’ small molecule drugs, as well as the technologies that empower them. Students will learn regulatory processes that govern medicine discovery and development and also consider business and societal aspects of medical progress. Students will be able to apply concepts directly to work in the healthcare industry.

**REG 610 Fundamentals of FDA Regulation**

This introductory course provides an overview of Regulatory Affairs in relation to three key areas of development: Drugs, Biologics, and Medical Devices. The course will look at the rules governing prescription and over-the-counter drugs as well as the changes introduced by the influence of genetic engineering and biological product development. The developmental and regulatory path for new devices, as well as the way products are governed once in the marketplace will be explained. Throughout the course, practical issues facing regulatory specialists as they work with the FDA and other international regulatory bodies to secure and keep product approval will be addressed.

**REG 611 Clinical Study Management**

This course will focus on the practical aspects of executing clinical trials in an academic environment in a GCP compliant fashion. Upon course completion students will be able to effectively implement and manage both investigator-initiated and industry-sponsored clinical research studies. Students will be guided through the operational aspects and regulatory processes for the three stages of study management: pre study, study start-up and implementation, ongoing compliance and study close out. Students will learn strategies for navigating the complex regulatory/operational clinical research environment and for successful protocol development and approval, subject recruitment, data management and IRB/FDA interactions. Protection of human research subjects and adherence to good clinical practices guiding research in humans is a critical concept that will be integrated throughout each of the lectures.
• REG 612 Intro to Drug Development
  o This introductory course lays the foundation for conducting pharmaceutical research in many ways. It begins with a brief review of the history of drug development and explains the phases of drug development in detail. The decision making process, drug development milestones and compound progression metrics are defined and explained with examples. At the conclusion of this course, students should have a working knowledge of the drug development process, understand the regulatory basis by which new chemical entities are evaluated and ultimately approved and appreciate the time and expense of drug development.

• REG 614 Biopharmaceutical Development, Manufacturing, and Regulatory Affairs
  o The course is designed to provide an overview of biopharmaceutical protein drug development and manufacturing processes with an emphasis on regulatory affairs activities.

• REG 630 Clinical Trials
  o This course will emphasize trial design issues. This is not a course on the biostatistics of clinical trials. It is expected that at the conclusion of the course, a student will be able to plan a clinical trial.

• EPID638 Topics in Clinical Trial Design & Analysis
  o This course is intended to follow and be complementary to EPID 630: Clinical Trials. It will build on the basic principles of design, conduct, and analysis introduced in that course and will go into more detail on particular approaches. Topics covered will include noninferiority trials, phase 1 designs, multi-stage and other adaptive designs, graphical data presentations and current ethical controversies in clinical trials.

Entrepreneurial Science

Concentration Director: Nalaka Gooneratne, MD, MSc

For students who aim to navigate both business and academic environments as you conduct research and consider commercialization opportunities.

Required Courses:
1.) MTR 640 Entrepreneurial Science Seminar .5 c.u.
  o This course reviews a broad range of topics related to establishing a successful career as an academic entrepreneur. The goal is to help students successfully navigate both business and academic environments as they conduct research on their concept, and consider commercialization opportunities.

2.) HCMG 867 Healthcare Entrepreneurship .5 c.u.
  o The course focuses on the creation, funding, and management of biotechnology and health services enterprises. The course is designed to supplement other offerings in
the Health Care Systems and Management Departments for those students with entrepreneurial interest in such ventures, and will focus on special issues surrounding the conceptualization, planning, diligence and capitalization, launch, compensation and management of these ventures. In addition, course offers methods for self-assessment & development of business models and plans, techniques for technology assessment and strategy, develops foundation for capitalization and partnering strategies, and creates a basis for best practices in company launch and plan execution.

Suggested Electives (Choose 1 c.u.):

- MTR 606 Grantsmanship or MTR 623 Writing an NIH Grant
- MTR 624 SBIR/STTR Grants
  - In development
- MTR 620 Commercializing Translational Therapeutics
  - To provide an in-depth view of the process by which scientific discoveries are commercialized. This course covers discovery in the laboratory, technology transfer, regulatory, financial, and managerial issues involved in moving a technology from the lab into the market place.
- HCMG 853 Medical Devices
  - Successful medical devices are an amalgamation of creative and innovative thinking, clinical expertise, and engineering know-how that endures intense regulatory and reimbursement scrutiny. This course will provide a foundation for understanding the nuances of the medical device industry. It will cover topics ranging from device design and discovery, regulatory issues, marketing, reimbursement, management, and strategy
- N573 Innovation in Health: Foundations of Design Thinking
  - Innovation, defined as a hypothesis-driven, testable, and disciplined strategy, is important to improve health and healthcare. Employing new ways of thinking, such as with design thinking, will help open up possibilities of ways to improve health and the processes of healthcare. Additionally, incorporating current and emerging social and digital technologies such as mobile applications (“apps”), wearables, remote sensing, and 3D printing, affords new opportunities for innovation. This course provides foundational content and a disciplined approach to innovation as it applies to health and health care.
- HCMG 863 Management and Economics of the Pharmaceutical & Biotech Industries
  - This course provides an overview of the management, economic and policy issues facing the pharmaceutical and biotechnology industries. The course perspective is global, but with emphasis on the U.S. as the largest and most profitable market. Critical issues we will examine include: R&D intensive cost
structure with regulation and rapid technological change; strategic challenges of
biotech startups; pricing and promotion in a complex global marketplace where
customers include governments and insurers, as well as physicians and
consumers; intense and evolving M&A, joint ventures, and complex alliances;
government regulation of all aspects of business including market access,
pricing, promotion, and manufacturing.

- MGMT 892 Collaborative Innovation Program
  - Provides opportunity to gain hands-on experience with innovation management
    challenges within an established firm. The institute’s corporate partners have
    proposed current business challenges; students selected for the program will
    form teams to work on addressing these challenges. Guided by Professor Ren,
    students may provide the following: industry analysis, competitor analysis,
general environment analysis (trends and uncertainties including political,
technological, global, and sociocultural segments), and assessment of the
organization’s internal strengths and weaknesses.

- EAS 545 Engineering Entrepreneurship I
  - The first of the two courses investigates key entrepreneurial areas of: (a)
    intellectual property, its protection and related strategies; (b) evaluating the
    market viability of new high-tech ideas; (c) shaping high-tech ideas into the right
    products or services for the right markets; (d) developing strategies for high-
techn product positioning, marketing and operations; (e) acquiring the resources
    needed to start a new venture, e.g., people, financing, strategic partners, etc.; and
    (f) leadership roles for the founders of high-tech ventures.

- EAS 546 Engineering Entrepreneurship II
  - The second of the two courses investigates the key elements of planning an
    entrepreneurial high-tech venture including: (a) defining the venture’s industry
    and market; (b) developing strategies for high-tech product positioning,
    marketing, distribution, sales, operations, management and development; and
    (c) preparing a financial plan.

**Bioinformatics/Biomedical Informatics**

Concentration Director: Benjamin Voight, PhD

*For students who are adopting informatics methodologies to develop and test their own hypotheses.*

Required Course (Choose 1):
  - MTR 535 Introduction to Bioinformatics
    - This course provides broad overview of bioinformatics and computational biology
      as applied to biomedical research. A primary objective of the course is to enable
      students to integrate modern bioinformatics tools into their research activities.
Course material is aimed to address biological questions using computational approaches and the analysis of data.

- **BMIN 503 Data Science for Biomedical Informatics**
  - Data science refers broadly to using statistics and informatics techniques to gain insights from large datasets. Biomedical informatics refers to a range of disciplines that use computational approaches to analyze biomedical data to answer pre-specified questions as well as to discover novel hypotheses. In this course, we will use R and other freely available software to learn fundamental data science applied to a range of biomedical informatics topics, including those making use of health and genomic data.

Suggested Electives (Choose 1 c.u.):

- **MTR 606 Grantsmanship or MTR 623 Writing an NIH Grant**
- **BMIN 501 Introduction to Biomedical and Health Informatics**
  - This course is designed to provide a survey of the major topics areas in medical informatics, especially as they apply to clinical research. Through a series of lectures and demonstrations, students will learn about topics such as databases, natural language, clinical information systems, networks, artificial intelligence and machine learning applications, decision support, imaging and graphics, and the use of computers in education.
- **BSTA 787 Statistical Methods for Genomic Data Analysis**
  - This course covers statistical, probabilistic and computational methods for analyzing high-throughput genomic data. With the advent of inexpensive DNA sequencing, statistical genetics is undergoing the transition to big data.
- **BMIN 502 Databases in Biomedical Research**
  - This course is intended to provide in-depth, practical exposure to the design, implementation, and use of databases in biomedical research. This course is intended to provide students with the skills needed to design and conduct a research project using primary and secondary data. Topics to be covered include: database architectures, data modeling approaches, data normalization, database implementation, client-server databases, concurrency, validation, Structured-Query Language (SQL) programming, reporting, maintenance, and security. All examples will use problems or data from biomedical domains. MySQL will be used as the database platform for the course, although the principles apply generally to biomedical research and other relational databases.