
MASTER OF SCIENCE IN REGULATORY SCIENCE

STUDENT HANDBOOK



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OVERVIEW

The Master of Science in Regulatory Science (MSRS) is housed within the Institute for Translational Medicine and Therapeutics (ITMAT). The objectives of ITMAT are (i) to cluster, expand, and democratize access to the resources relevant to the conduct of translational medicine and therapeutics and to sustain and expand a visible home for this emerging discipline; (ii) to increase the number of investigators capable of pursuing translational research through novel educational programs and targeted recruitments to Penn; (iii) to identify and minimize the obstacles faced by investigators conducting clinical and translational science (CTS) and (iv) to enhance clinical implementation of the discoveries of translational research. Expanding the number of investigators trained in regulatory science is key to the success of these initiatives.

There is increasing global demand for trained scientists who work in Academia, Biotech, Pharma, the FDA, and similar global regulatory agencies who are adept at applying knowledge of scientific and regulatory strategy to the design and execution of research portfolios focused on all strategies of product (drug, biologic, and device) development.

The Masters of Science in Regulatory Science is designed to provide training in scientific and regulatory strategy to those who aim to pursue careers as regulatory scientists working on product development in Academia, Biotech, Pharma, the FDA and equivalent global regulatory agencies.

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 Master's Programs to the PSOM Office of Master's and Certificate Programs. The daily operations of the MSRS program are the responsibility of the ITMAT Education Program under the direction of Emma Meagher, MD, and the Program Director, Andrew Fesnak, MD.

Program Objectives

The primary objective of the Master of Science in Regulatory Science (MSRS) degree program is to produce a cadre of highly trained and sophisticated investigators adept in the skills necessary to become leaders in the field of regulatory science.

The MSRS provides trainees with in-depth instruction in the fundamental skills, methodology, and principles necessary to become a well trained investigator positioned for a future career as a successful academic researcher. The program is designed to meet these objectives through:

- The provision of didactic course work,
- A primary thesis project,
- A formal mentorship program,

Specific ongoing guidance with hands-on exposure to protocol and grant development.

Program Goals

Upon successful completion of the MSRS program, graduates are expected to have developed a strong foundation in the fundamental techniques of research. They should be able to apply contemporary research tools to relevant areas of investigation. MSRS trainees will 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 this training.

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 MSRS 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.

ACADEMIC PROGRAM

Master of Science in Regulatory Science Degree Requirements

The MSRS degree is composed of 12 course units

4 core courses (4 c.u.)

1. REG 600 Introductory Biostatistics
2. REG 602 Proposal Development
3. REG 604 Scientific and Ethical Conduct
4. REG 610 Fundamentals of FDA Regulation

2 regulatory core courses (2 c.u.)

1. REG 611 Clinical Study Management
2. REG 612 Introduction to Drug Development
3. REG 630 Clinical Trials
4. REG 614 Biopharmaceutical Development, Manufacturing, and Regulatory Affairs
5. REG 615 Post-Approval Maintenance of Drugs, Devices, & Biologics

4 elective courses (4 c.u.)

2 thesis credits (2 c.u.)

Description of Required Course Work

REG 600 Introductory Biostatistics: 1 c.u. (Fall session –year one)

This course will use elements of statistics as a vehicle through which to: better understand, absorb, and adjudicate information from the peer review literature; assess the best analytic approach to interrogate scientific hypotheses; develop the necessary vocabulary needed to engage with professional statisticians, and create your own independent critical thinking lens.

REG 602 Proposal Development: 1 c.u. (Summer II semester - year one)

This course focuses on study design and proposal development as they relate to the studies that probe the mechanism of disease. It discusses concepts such as writing a background section, asking a research question, designing a study, use of biomarkers, writing a research proposal, overview of different study designs and addressing feasibility issues. Development of the thesis proposal starts during this course and concludes with each student submitting and presenting their proposal to the MSRS faculty panel, the students research mentor(s), and thesis committee for critique and feedback.

REG 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, 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.

REG 610 Fundamentals of FDA Regulation: 1 c.u. (Summer 11 week session – year one)

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 641 & 641 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.

Internship Program: The MSRS 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. This program will foster greater interactions between industry and academia by exposing MSRS 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 (REG 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.

Description of Regulatory Core Courses

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 Introduction to Drug Development

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

Biopharmaceutical protein products have been successfully used to treat a number of diseases and currently represent a large segment of the product pipeline in most major pharmaceutical companies. More than half of the current top 20 blockbuster drugs are biopharmaceuticals. Drugs like Activase®, Humira®, and Avastin® have revolutionized the drug industry in treating the unmet medical needs of many patients. With innovation at the heart of the biopharmaceutical industry, this course is aimed at developing the student's understanding of the application of basic research in molecular biology and genetics to the development of novel drugs for treating diseases. The course is designed to provide an overview of biopharmaceutical protein drug development and manufacturing processes with an emphasis on regulatory affairs activities. The class has been developed and is taught by a former VP of biopharmaceutical product development with over 30 years of experience in biotechnology and the biopharmaceutical industry. The course director will provide insights into the unique challenges and opportunities facing the biopharmaceutical industry and how they relate to regulatory affairs. Subject area experts from industry will also participate as guest lecturers.

REG 615 Post-Approval Maintenance of Drugs, Devices, and Biologics

The FDA regulates prescription drugs, biologics and medical devices for utilization in the United States. The approval of a marketing application is a major accomplishment; however, it comes with significant responsibilities for a sponsor including numerous reporting requirements and activities to maintain a license, as well as a need for lifecycle maintenance activities to stay competitive. The purpose of this course is to provide an overview of post-approval activities required for drugs, biologics and devices, including topics such as understanding pertinent US regulations, general requirements for license maintenance, key periodic reports submitted to regulatory agencies, types of post-approval changes, and reporting categories for post-approval changes and reporting procedures.

Description of Elective Course Work

In addition to the required courses, students must enroll in four electives that total four 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 MSRS 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 MSRS 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.*

REG 660 Independent Study: 1 c.u.

MSRS students may perform an independent study for credit based on meeting specific educational requirements. All independent study courses require a designated MSRS 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 MSRS curriculum committee are eligible to be REG 660 course directors. MSRS 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 MSRS 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 MSRS 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.

Sample of a Plan of Study

Year	Summer	Fall	Spring	Professional Development Core
1	Summer Session II REG 602 REG 999	REG 600 REG Core Course	REG 604 Elective 1	

2	REG Core Course Elective 2 <i>session 2</i>	REG 641 Elective 3	REG 642 Elective 4	
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MENTORING

An essential component of the MSRS 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 MSRS 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 MSRS degree program have a Mentoring Committee. This is composed of the primary research mentor and a programmatic mentor. The student may elect to have a secondary research 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 MSRS 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. Students should discuss their needs with their mentoring committee.

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.

RESEARCH PROJECT AND THESIS

The primary focus of MSRS projects is scientific endeavors that operate in and navigate through the regulatory environment. Projects are an opportunity to demonstrate capacity for scientific rigor, experimental design, data analysis, manuscript preparation, good laboratory practices and overall academic productivity.

Research training is an integral component in the preparation of physician-scientists for career advancement as scientific professionals. The MSRS 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 when possible 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 regulatory science 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 MSRS 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.

MSRS Sample Thesis Projects

- Develop lab-developed test for CoV2 through regulatory approval for implementation as clinical test in UPHS
- Develop high resolution companion diagnostic for anti-GD2 CAR T cell monitoring in humans
- Develop and study implementation of genomic profile testing for P450 enzymes in a academic medical center

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 the resources available to the student in the MSRS 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 regulatory science 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 their own data and appropriately interpret the results.
4. Appreciates where their 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 their 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 beginning the program. The committee consists of three faculty who are experts in the research area but have no direct influence on a student's project. They should not be the student's department chair or division chief or a research, lab, or program mentor. The thesis committee members will provide feedback on the student's research proposal from inception, attend the proposal presentation and complete an evaluation of the presentation, provide additional feedback on the project throughout the MSRS program, and will ultimately serve as a reviewer for the thesis defense. At the time of the defense, the student and the mentoring team will evaluate if the committee is still appropriate. 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 MSRS administrative office.

Students will manage committee engagement. Students should establish the frequency of meetings based on research progress and/or roadblocks that require input for critical decision points.

Laboratory Research for MSRS Students

As an *elective*, students may decide 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 regulatory components of the translational research experience. The focus should be on regulatory and compliance underpinnings of translational research as well as regulatory and policy implications of findings in the area of human research.

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 REG 999 Unit. To get approval, students should complete the **lab proposal form** found on the 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 REG 999 unit by the MSRS Administrative Office**. The Lab Rotation approval must be received **prior** to commencing the lab rotation.

REG 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>.

Penn also offers an electronic research notebook through LabArchives:

<https://researchnotebooks.upenn.edu/>

Lab Report and Grading

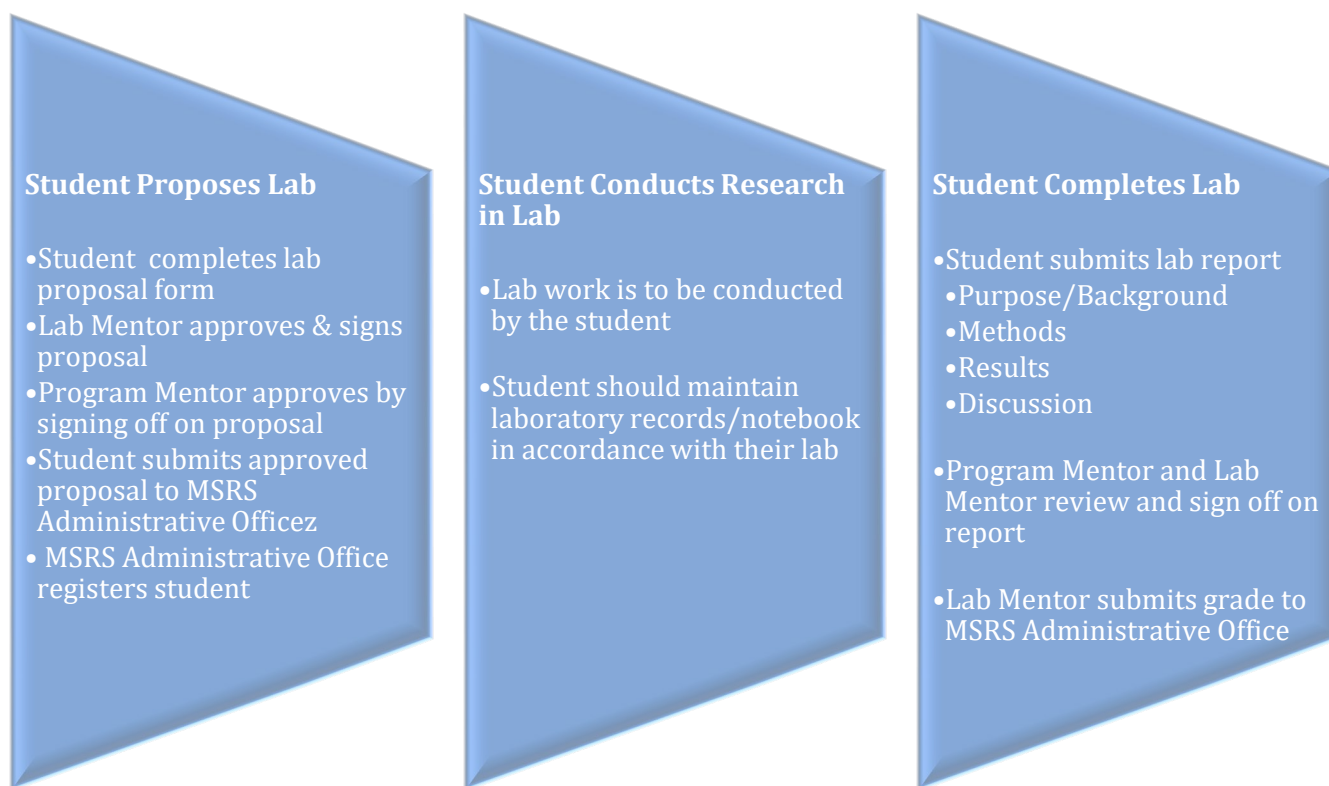
At the end of the lab, students are required to write a **1-3-page report** by completing the REG 999 Lab Report Template (found on the MSRS Canvas webpage) that outlines the:

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

The quality of the written report should be sufficient for incorporation into the MSRS 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.

REG 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:



Conduct of the Research

The student will 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 their 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 their 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 MSRS 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 MSRS 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 MSRS 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 MSRS theses will be submitted for publication and a copy of the final paper should be submitted to the MSRS 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 MSRS program website to identify if it is required to acknowledge grant support.

http://www.itmat.upenn.edu/Citing_ITMATEd_Funding.html

Procedures for Changing the Thesis

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 MSRS 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 MSRS 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 the above-mentioned steps must be taken before the project is acceptable as a thesis.

MSRS POLICIES

Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure. At the MSRS 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 MSRS 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 (REG 999) and Thesis Credits (REG 641, 642) 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 MSRS 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 may be placed on academic probation. Students may continue to enroll in other courses while on probation with the permission of the MSRS 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 MSRS Curriculum 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 original grade may not be changed. Additional remediation may be required based on the judgment of the program director, the student’s advisor, 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 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 MSRS program, whether it concerns a course, instructor, or mentorship, are encouraged to come to the MSRS Program Office (8035 Maloney Bldg, HUP) to discuss their concern. Alternatively, the student may wish to speak directly with their Programmatic Mentor and/or the MSRS Program Director.

Transfer Credit Policy

Twelve course units including completion of two thesis credits are required for the MSRS degree. MSRS 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 laboratory course units. 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 MSRS Program Director together with a course syllabus for the course under consideration. The director will request a review of the course by a MSRS faculty member in that content area for its appropriateness for MSRS 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 MSRS degree. If a student wishes to change a course status from credit to audit, they 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 ended. *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

MSRS 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/>). 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>

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. The most recent version of the code is located here: <https://catalog.upenn.edu/pennbook/code-of-academic-integrity/> 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.

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 MSRS 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 MSRS degree is 5 years from the date of matriculation.

Registration

Continuous Registration and Leave of Absence

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.

A student who wishes to take a leave of absence must submit a written request to the MSRS 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.

Registration Process

The MSRS administrative office is responsible for registering all students for MSRS 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 MSRS Mentoring Committee then contact the course instructor to request permission to enroll. Once the instructor grants permission, then the student must notify the MSRS 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 MSRS administrative office by the registration deadline.

To register for the industry internship, students must arrange the experience with the MSRS administrative office.

To register for independent study, students must submit a proposal to their MSRS program mentor. After receiving approval, the proposal and approval must be submitted to the MSRS administrative office before the registration deadline.

Students are required 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 MSRS courses visit the MSRS website at: <https://www.itmat.upenn.edu/msrs/>

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

ADMINISTRATIVE REQUIREMENTS

Throughout the program, students will be required to keep track of and follow through on all administrative requirements for the MSRS 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 MSRS 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 MSRS 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 MSRS program. Students will receive an email with a survey link from the MSRS administrative office.
- 4) MSRS Surveys – students are required to complete an online evaluation of the MSRS program each year. You will receive an email with a survey link from the MSRS 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.

To learn more, contact the Office of Clinical Research <https://www.med.upenn.edu/ocr/about.html>

UNIVERSITY OF PENNSYLVANIA SYSTEMS

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 MSRS 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 MSRS courses and by the University. Individual pages are set up for each MSRS Course and can be accessed with PennKey and Password.

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

Support: canvas@pobox.upenn.edu

FINANCIAL INFORMATION

Description of Fees

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

For current tuition rates, visit <https://srfs.upenn.edu/costs-budgeting/med/masters>

General Fee: 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 (enrolled in more than 2 c.u. in a term) 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>

MSRS ADMINISTRATIVE STRUCTURE

The institutional governance and oversight of the Master of Science in Regulatory Science 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 MSRS program is the Institute for Translational Medicine and Therapeutics (ITMAT).

The Participating Schools in the MSRS program are the Schools of: Medicine, Veterinary Medicine, Nursing, Engineering 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 MSRS students and is the chairperson of the Curriculum and Selection Committees. The current Program Director is Andrew Fesnak, MD.

The MSRS Curriculum Committee serves generally to advise the program leadership on all matters related to implementation and evaluation of the MSRS program and other related activities. The curriculum committee is responsible for formal decision-making on academic aspects of the MSRS 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 MSRS program, monitoring the work of the standing committees, recruiting faculty for the program, and developing liaisons with appropriate Penn centers and institutes.

The MSRS Selection Committee meets to identify new MSRS 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.