



**ITMAT**

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**Institute for Translational Medicine  
and Therapeutics**

**2022-2023 ITMAT  
Education Certificates  
Handbook**

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## Introduction

Certificate programs are one of many educational offerings from ITMAT Education, the training arm of the Institute for Translational Medicine and Therapeutics. They offer various paths to advancement in translational and clinical research for professionals including pre- and post-doctoral scholars, as well as individuals working in the field and in industry. Ultimately, they serve to enable a clinical and translational research workforce to move more discoveries from the bench to the bedside.

The certificates vary in audience, coursework, and focus.

## Certificate Options

ITMAT Education offers four (4) certificate programs, each serving different scholar populations.

All ITMAT Education certificates:

- Require the completion of 4 course units (CUs)
- Require two (2) core courses and two (2) electives
- Are designed to be completed within one year
- Are designed for part-time study to maximize scholars' ability to complete the curriculum while working full-time

### Certificate in Translational Science, Entrepreneurial Science, or Regulatory Science

The certificates in translational science, entrepreneurial science, and regulatory science are designed for members of the existing Penn Medicine community. These programs are designed for PhD scientists (pre-docs, post-docs, and occasionally junior faculty) who wish to pursue careers in academia, the pharmaceutical & biotechnology industry, the consulting and legal industries, and federal agencies, among other areas. The coursework for these certificates may be a blend of online and face-to-face learning, depending on a scholar's chosen electives and courses.

Pre-doctoral PhD students are encouraged to apply to the certificate and associated training grant. The CTSA TL1 award provides one year of funding including tuition and a stipend per NIH policy. The tuition funding will cover the cost of the certificate.

The differences between these three certificates lies in the scholar's chosen research project, which will align best with one of the three subject areas. The core coursework and elective coursework will also shape the different certificates' subject areas.

### Certificate in Regulatory Affairs

The certificate in regulatory affairs is designed for clinical research professionals, whether in the Penn community or external members working in industry, to develop learners' knowledge and skills necessary to bring medical products to market that are safe and effective. Graduates will be able to describe ways to maximize compliance and minimize risk in the development of FDA-regulated products and learn the foundation of science-based clinical investigation and corresponding regulations. The online format will allow students to seamlessly transition from work to evening classes and to engage with peers, faculty, and content in meaningful ways.

The certificate can be taken as a standalone or, if interested, students are welcome to complete the certificate and then apply to the Master of Regulatory Affairs program with a waived fee at the time of the MRA application. The regulatory affairs certificate is not a funded program, though scholars may use any tuition benefits or reimbursement offered by their employers. The certificate is offered with entirely online courses, making it accessible to students across the U.S. in a variety of settings.

The certificate in regulatory affairs requires a bachelor’s degree and at least 6-12 months of experience in the field of regulatory affairs. (It does not require doctoral study or credentials, unlike the other certificate programs.)

## Certificate Academic Requirements

The University of Pennsylvania operates on an academic semester system. The ITMAT Education certificate programs each require 4 course units for completion, with 2 core courses, 2 electives. Three of the certificates (Translational Science, Regulatory Science, and Entrepreneurial Science) require the completion of a concurrent research project.

The core courses are taught once per year in the semester designated in the study plans below. Each certificate is outlined below in a study plan. Course descriptions are also included to assist you in selecting a certificate.

### Certificate in Translational Science: Courses and Study Plan

| <b>COURSES</b>  | <b>COURSE UNITS</b> |
|---|---------------------|
| <b>MTR 5100</b> INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH | 1.0                 |
| <b>MTR 6000</b> INTRODUCTION TO BIOSTATISTICS                       | 1.0                 |
| ELECTIVES (2 CU)  | 2.0                 |
| RESEARCH PROJECT (CONCURRENT WITH COURSES)                          | 0.0                 |

#### STUDY PLAN

| <b>FALL</b>   | <b>SPRING</b> |
|---|---------------|
| <b>MTR 5100</b> INTRO CLINICAL AND TRANSLATIONAL RESEARCH | Elective      |
| <b>MTR 6000</b> INTRO TO BIOSTATISTICS                    | Elective      |

### Certificate in Regulatory Science: Courses and Study Plan

| <b>COURSES</b>  | <b>COURSE UNITS</b> |
|---|---------------------|
| <b>REG 5100</b> INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH | 1.0                 |
| <b>REG 6100</b> FUNDAMENTALS OF FDA REGULATION                      | 1.0                 |
| ELECTIVES (2 CU)  | 2.0                 |
| RESEARCH PROJECT (CONCURRENT WITH COURSES)                          | 0.0                 |

**STUDY PLAN**

| FALL YEAR 1   | SPRING YEAR 1 | SUMMER YEAR 1                                  | FALL YEAR 2 |
|---|---------------|--|-------------|
| <b>REG 5100</b> INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH | Elective      | <b>REG 6100</b> FUNDAMENTALS OF FDA REGULATION | Elective    |

## Certificate in Entrepreneurial Science: Courses and Study Plan

| COURSES   | COURSE UNITS |
|---|--------------|
| <b>MTR 5100</b> INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH | 1.0          |
| <b>MTR 6000</b> INTRODUCTION TO BIOSTATISTICS                       | 1.0          |
| ELECTIVES (2 CU)  | 2.0          |
| RESEARCH PROJECT (CONCURRENT WITH COURSES)                          | 0.0          |

**STUDY PLAN**

| FALL                                    | SPRING   |
|---|----------|
| <b>MTR 5100</b> INTRO CLINICAL RESEARCH | Elective |
| <b>MTR 6000</b> INTRO TO BIOSTATISTICS  | Elective |

## Certificate in Regulatory Affairs: Courses and Study Plan

| COURSES   | COURSE UNITS |
|---|--------------|
| <b>REG 5100</b> INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH | 1.0          |
| <b>REG 6100</b> FUNDAMENTALS OF FDA REGULATION                      | 1.0          |
| ELECTIVES (2 CU)  | 2.0          |

**STUDY PLAN**

| FALL  | SPRING   | SUMMER   | FALL     |
|---|----------|--|----------|
| <b>REG 5100</b> INTRODUCTION TO CLINICAL AND TRANSLATIONAL RESEARCH | Elective | <b>REG 6100</b> FUNDAMENTALS OF FDA REGULATION | Elective |

**Note that the certificate in Regulatory Affairs, unlike the other certificates, does not require a research project.**

## Course Descriptions

REG/MTR 5100 Introduction to Clinical and Translational Research

\*Required for all certificates

This introductory course lays the foundation for understanding practical aspects of conducting clinical research in an academic environment. The course is divided into two modules: Module 1: Research Methods & Protocol Development and Module 2: Regulatory Environment for Clinical Trials. The first module introduces clinical research, clinical protocols, study designs and biostatistics that underlie such studies. The second module covers ethical considerations in clinical research, study execution and

oversight, and the regulatory environment for clinical research. Upon completion, students should have a strong foundation in the fundamentals of clinical research and should be able to apply contemporary research tools to clinically relevant areas of investigation.

### REG 6100 Fundamentals of FDA Regulation

\*Required for certificates in Regulatory Affairs and Regulatory Science

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.

### MTR 6000 Introductory Biostatistics

\*Required for certificate in Translational Science and Entrepreneurial Science

The goal of this course is to develop translational scientists who are able to apply the necessary statistical methods to their thesis project, critically assess the application of statistical methods in the literature, and collaborate with biostatisticians. The course will be designed to include weekly seminars to teach introductory biostatistics concepts and group assignments applying the principles through critically assessing the literature.

## Approved Electives

The following electives have been approved for the MRA degree program. The electives are categorized by concentration. All REG electives are offered in an online format. Courses taken as electives in other program may be in-person and require students to come to campus unless otherwise noted.

| <b>COURSE NAME</b>                                     | <b>Approved for<br/>Translational<br/>Science</b> | <b>Approved for<br/>Entrepreneurial<br/>Science</b> | <b>Approved for<br/>Regulatory<br/>Science</b> | <b>Approved for<br/>Regulatory<br/>Affairs</b> |
|--|---|---|--|--|
| <b>REG 6100</b> Fundamentals of<br>FDA Regulation      | X   | X   |  |  |
| <b>REG 6110</b> Clinical Study<br>Management           | X   |   | X  | X  |
| <b>REG 6150</b> Post-Approval<br>Maintenance           |   |   |  | X  |
| <b>REG 6120</b> Intro to Drug<br>Development           | X   |   | X  | X  |
| <b>REG 6160</b> Quality Assurance                      |   |   |  | X  |
| <b>REG 6180</b> Introduction to<br>Vaccine Development | X   |   | X  | X  |
| <b>REG 6210</b> Cell & Gene<br>Therapy                 | X   |   | X  | X  |



| <b>COURSE NAME</b>  | <b>Approved for<br/>Translational<br/>Science</b> | <b>Approved for<br/>Entrepreneurial<br/>Science</b> | <b>Approved for<br/>Regulatory<br/>Science</b> | <b>Approved for<br/>Regulatory<br/>Affairs</b> |
|---|---|---|--|--|
| <b>REG 6220</b> New Trends in<br>Medicine & Vaccine<br>Discovery                                    | X   |   | X  | X  |
| <b>REG 6240</b> Applied Regulatory<br>Processes of Vaccines and<br>Biologics                        | X   |   | X  | X  |
| <b>REG 6250</b> Manufacturing<br>Novel Therapies & Imaging<br>Agents                                | X   |   | X  | X  |
| <b>REG 6260</b> Drug Development<br>for Patent Law  |   |   | X  | X  |
| <b>HCMG 8990</b> Management &<br>Economics of the Pharma,<br>Biotech & Medical Device<br>Industries |   |   |  | X  |
| <b>PUBH 5020</b> Introduction to<br>Epidemiology  |   |   |  | X  |
| <b>LAW 5110</b> Intro to US Law<br>and Legal Methods  |   |   |  | X  |
| <b>LAW 5220</b> Compliance and<br>Corporate Governance  |   |   |  | X  |
| <b>LAWM 5360</b> Fundamentals<br>of US Legal Research ( <i>online</i> )                             |   |   |  | X  |
| <b>LAW 5290</b> Navigating the<br>Regulatory State  |   |   |  | X  |
| <b>LAW 5300</b> Intro to Health<br>Law & Policy   |   |   |  | X  |
| <b>LAW 9200</b> Pharmaceutical<br>Regulation & Enforcement  |   |   |  | X  |
| <b>BMIN 5010</b> Intro to<br>Biomedical Informatics   |   |   |  | X  |
| <b>BMIN 5020</b> Databases in<br>Biomedical Research  |   |   |  | X  |
| <b>BIOE 5520</b> Bioethics & the<br>Law   |   |   |  | X  |
| <b>BIOE 5750</b> Health Policy  |   |   |  | X  |
| <b>MTR 6010</b> Scientific Writing I  | X   |   |  |  |
| <b>MTR 6020</b> Proposal<br>Development & Study Design  | X   |   |  |  |
| <b>MTR 6030</b> Disease<br>Measurement  | X   |   |  |  |
| <b>MTR 6040</b> Scientific and<br>Ethical Conduct   | X   |   |  |  |
| <b>MTR 6050</b> Scientific Writing II   | X   |   |  |  |

| <b>COURSE NAME</b>  | <b>Approved for<br/>Translational<br/>Science</b> | <b>Approved for<br/>Entrepreneurial<br/>Science</b> | <b>Approved for<br/>Regulatory<br/>Science</b> | <b>Approved for<br/>Regulatory<br/>Affairs</b> |
|---|---|---|--|--|
| <b>MTR 6600</b> Independent Study   | X   |   |  |  |
| <b>MTR 6060</b> Grantsmanship   | X   |   |  |  |
| <b>MTR 5350</b> Intro to Bioinformatics   | X   |   |  |  |
| <b>MTR 6200</b> Medical Entrepreneurship: Commercializing Translational Science | X   | X   |  | X  |
| <b>MTR 6230</b> Writing an NIH Grant  | X   |   |  |  |
| <b>MTR 6400</b> Entrepreneurial Seminar   | X   | X   |  |  |
| <b>HCMG 8670</b> Healthcare Entrepreneurship                                    |   | X   |  |  |
| <b>CHEM 742</b> Medical Chemistry & Drug Decision                               |   |   | X  |  |

### Research Project

The certificates in Translational Science, Regulatory Science, and Entrepreneurial Science each require a one-year engagement in a discipline-related research project. This will take the form of a new research project or as an additional arm to research currently being conducted. If the student is already engaged in regulatory, entrepreneurial, or translational science, an additional research project is not required. Prospective students will identify a mentor and define the research project at the time of application.

Meanwhile, the certificate in Regulatory Affairs does **not** require a research project.

## Academic Policies

### Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure. Letter grades may be modified by a plus (+) or minus (-) sign at the discretion of the course director. The typical grade scale is as follows but may vary based on the course director.

| LETTER GRADE | PERCENT SCORE |
|--------------|---------------|
| <b>A</b>     | 93-100        |
| <b>A-</b>    | 90-92         |
| <b>B+</b>    | 87-89         |
| <b>B</b>     | 83-86         |
| <b>B-</b>    | 80-82         |
| <b>C+</b>    | 77-79         |
| <b>C</b>     | 73-76         |
| <b>C-</b>    | 70-72         |
| <b>D+</b>    | 67-69         |
| <b>D</b>     | 63-66         |
| <b>D-</b>    | 60-62         |
| <b>F</b>     | 0-59          |

At the graduate level for the ITMAT Education certificate programs, the grade of C, while passing, does not constitute satisfactory performance. The minimum standard for satisfactory work in each course is a B-. The program additionally requires that the quality of the student's 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 their 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 both core courses and electives. 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. If a student has at minimum 2 incompletes on their academic transcript, the student is ineligible to register for future courses and must meet with program leadership to develop a plan for how the incompletes will be resolved.

## Academic Standing

ITMAT Education has specific academic standards that are expected of all students. If a student fails to obtain a B- or better 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 appropriate 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 Program Curriculum Committee as needed.

A remediation 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 into the student record system (SRS) will not be changed. Additional remediation may be required based on the judgment of the Program Director, the Program Curriculum Committee, and/or the course directors. A student who is or has previously been on probation and who receives an unacceptable grade for an additional course may be reviewed by the Program Director and the Program Curriculum Committee. The committee is authorized to dismiss the student or allow the student to remain in the program on a probationary status.

## Academic Grievances

Instructors and faculty members have the authority to make academic judgments in relation to their students. Therefore, if a graduate student wishes to have an evaluation, exam, or course grade reviewed, they must first discuss the matter with their instructor. Should the student and instructor not find a satisfactory resolution, or should a discussion prove impossible, the student may submit a request in writing to the Program Director.

Should the matter not be resolved with the aid of the Program Director, students may ask that their request be elevated to the Associate Dean for PSOM Master's and Certificate Programs for further review. The role of the Associate Dean is to ensure that the Program has arranged for a proper review of the matter and that the evaluation was fair and impartial and in accordance with relevant University policies.

## Transfer Credit Policy

Four course units are required for completion of an ITMAT Education certificate. Students may request to transfer credit for graduate level courses completed at the University or from an accredited program outside of the University. All transfer credit requests will be considered on a case-by-case basis.

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 another degree.

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

A student may opt to audit a course at the time of registration—by selecting Audit as the grade type—and may reverse this decision up until the Drop Deadline. The option to update registration is not available after the Course Selection Period closes, so students should contact their program staff. Audited courses are charged tuition, the same as regular courses, and do not count toward the degree. Students may not audit more than 49% of the coursework they are attempting in a term, in accordance with financial aid policies.

## Time Limitation

The certificate programs may be taken on a part-time basis. The timing of course work is optimized to permit students to continue in their employment while working toward the completion of the degree. The maximum time permitted to complete the certificates is 2 years from the date of matriculation.

## Registration

Students are responsible for registering themselves in program courses and electives outside of the chosen certificate. Program staff for each certificate program will provide registration deadlines, billing schedule reminders, and assistance to students registering for courses. Prior to registering for courses students will meet individually with their program staff to develop their study plan. Students should use the study plan to guide them in registering for courses each semester. Students are required to verify course registration, tuition bills and grades through the student portal [Path@Penn](#).

Students may refer to the Penn Three-Year Academic Calendar to find out registration dates and add/drop periods on the [Registrar's website](#). Information on course offerings (e.g. timetables, classrooms, and course descriptions) may vary from the Registrar's website. For the most up-to-date information on courses, visit the [ITMAT Education courses page](#).

## Continuous Registration

Continuous registration as a graduate student is required unless a formal leave of absence is requested and granted by the Program Director. If an approved academic leave of absence is granted, at the discretion of the program, and may “stop the clock” on time to degree completion. The length of the leave is determined by the program based on program policies and individual circumstances. Students on leave should remain in contact with their program and provide updates about changes in plans. Students may not be required to complete any degree-related activities during a leave of absence. Exceptions may be made for repeating or completing coursework students have already attempted in previous terms. Such exceptions should be outlined in the leave of absence request and reflected in the approval letter. When preparing to return, students must consult with their program to develop a plan that includes the connection with appropriate resources and reactivation in the student record system.

The certificate degree programs are structured for completion in 1 year. Students may request an alternative plan of study to extend their planned time to degree. All students must complete the degree within 5 years. Failure to complete degree requirements will result in the student being dismissed from the program.

Students are required to register in each mandatory term of their degree these include the fall and spring terms. Students who do not plan to register during a mandatory term should request a leave of absence.

### Registration Timeline

Student registration may be adjusted through Path@Penn through the end of the Course Selection Period for each term, as listed in the term Academic Calendar. After the Course Selection Period ends, registration adjustments must be requested through the program administrators. There will be a financial penalty assessed for dropping a course after the Course Selection Period, following the scheme below:

|  |  |
|--|--|
| Drop on or before the Course Selection Period ends                       | 100% reduction of tuition & fees*  |
| Drop after the Course Selection Period ends and before the Drop Deadline | 50% reduction of tuition & fees*   |
| Drop after the Drop Deadline and before the Withdrawal Deadline          | 0% reduction in tuition & fees*<br>Mark of 'W' added to the transcript                                   |
| Drop after the Withdrawal Deadline                                       | 0% reduction in tuition & fees*<br>Mark of 'WF' on the transcript,<br>indicating Withdrawal with Failure |

\*Note to students with Penn Faculty / Staff Tuition Benefits: Tuition benefits are calculated based on the number of registered CU and are adjusted in accordance with registration. Tuition benefits are always reduced 100%, regardless of the date of the drop, meaning they will not cover partial tuition & fees left on the bill as a result of dropping a course after the Course Selection Period ends. The portion of tuition and fees remaining on the bill after courses have been dropped are the student's responsibility.

### Leave of Absence

A student may request a leave of absence at any time. A leave of absence may be granted by the program director for up to one year with the possibility of renewal. Students may wish to take a leave for various reasons, including but not limited to, personal circumstances, military service, health issues, or family medical leave. While on leave, students may access the library and other Penn resources upon paying a special fee each semester of the absence. Upon requesting a leave of absence, a student should provide a written request with an estimated date of return. Failing to register for coursework without permission from the University does not constitute a leave of absence. If the student requests leave after the start of the term, all normal drop and withdrawal policies apply.

When returning from a leave, students will contact their program thirty days before the start of the term in which they plan to return to confirm they are returning. If a student fails to return from leave within the set time limit or request a renewal, they will be dismissed from the program.

Leave of absence will affect any student loans—either those sought to pay for the degree or those from a previous academic career. This may include loans going into repayment before the end of the leave. Students are encouraged to talk to Student Registration and Financial Services prior to taking a leave of absence to ensure they have planned for shifting financial responsibility.

To request a leave of absence, contact your program staff.

## Withdrawal

Students may withdraw from their program at any time. Please contact your program for the appropriate form to commence official withdrawal proceedings. Students who are considering withdrawal are strongly encouraged to contact and meet with their Program Director to discuss their situation and options. Students are responsible for dropping all registered courses in the semester they wish to withdraw to effectively stop the billing process (in other words, withdrawal from the program does not automatically cancel course registration). Students are responsible for all tuition charges and other financial obligations to the University incurred prior to the effective date of withdrawal. Once students have withdrawn, they may reapply for admission under the program's application portal. Credit completed prior to readmission will be reviewed as transfer credit under the program's transfer credit policy.

## Drop from Program

A student may be dropped from their program for several reasons. Like a voluntary withdrawal, students will be responsible for any charges or financial obligations to the University incurred before the effective date of the drop.

1. **Time Limit:** Students are expected to complete their degree within 5 years of matriculation. Should a student fail to complete their degree within the time limit, the program will drop the student.
2. **Academic Progress:** Students are expected to maintain continuous registration, maintain a GPA of at least 3.0, carry incomplete marks for no more than a year, and achieve grades of B or better in all coursework. If a student does not meet these criteria, they may be placed on probation—with an opportunity to remediate issues with their progress—or dropped from the program.
3. **Academic Integrity:** Students are expected to follow the University Code of Academic Integrity. Violations of this code may result in the student being dropped from the program.
4. **Student Conduct:** Students are expected to follow the University Code of Student Conduct. Violations of this code may result in the student being dropped from the program.
5. A student dropped from their program will receive a letter stating that they have been dropped along with the reason for their drop.

## Student Conduct

ITMAT Education 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](#). 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.

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.

Additional codes of conducts and expectations students should be familiar with are the [nondiscrimination statement](#), the [sexual misconduct policy and resource offices](#), and [student grievance procedures](#).

## 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 Code of Academic Integrity can be viewed in the [PennBook](#) or below. 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 Code of Academic Integrity are reviewed by the Program Director and as necessary referred to the Penn Office of Student Conduct. If a student is unsure whether their 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.



## Students with Disabilities

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of [Student Disability Services](#). Please contact a MRA program staff (the Associate Director and/or Instructional Designer) as soon as possible in order to discuss your accommodations and your needs. If you would like to request accommodations or ask questions, make an appointment by contacting the office of Student Disability Services at 215-573-9235 or [vpul-sds@mail@pobox.upenn.edu](mailto:vpul-sds@mail@pobox.upenn.edu). The office of Student Disability Services is located in the Weingarten Learning Resources Center at Stouffer Commons, 3702 Spruce Street, Suite 300. All services are confidential.

## Religious & Cultural Holidays

Religious and cultural holidays are listed on the [University of Pennsylvania's Chaplain website](#). If a student observes any of the listed holidays and they conflict with a class date, please contact program staff with class date with which the holiday coincides. Please include the title of the holiday or religious observance in your message.

If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

If a student observes a holiday that is not listed, please inform program staff of this holiday and staff will make sure to include this moving forward.

## Administrative Requirements

Throughout the program, students will be required to keep track of and follow through on all administrative requirements for the certificate program. Below is a summarized list of the requirements:

1. **Course Evaluations** – Students are required to complete an evaluation for every course. Students will receive an email notification and website link to the online evaluation in the BLUE evaluation system during and/or at the end of each term. Grades will not be released until evaluations are complete.
2. **Surveys** – Students are required to complete an online evaluation of the program. You will receive an email with a survey link from program staff. Graduating students are required to complete an exit survey evaluating the program.
3. **Graduation Application** – Each certificate is conferred by the University of Pennsylvania Perelman School of Medicine and is granted in May, August, or December. In order to be considered for conferral of the degree, a student must complete a “graduation application” approximately three months prior to the expected conferral date. Prior to each graduation period, the program office will email details and deadlines to all eligible candidates.

## Research Regulations Compliance

Research regulations apply to students conducting research (typically only students enrolled in the certificates in Translational, Entrepreneurial, and Regulatory Science).

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](#).

## University of Pennsylvania Systems

### PennCard

PennCard is the official identification card of the University of Pennsylvania. Students in fully online programs (such as the Certificate in Regulatory Affairs) are **not** required to have a PennCard, but you may request one if you are local to Philadelphia or intend to visit campus. Students taking in-person courses (in any of the other certificates) are required to have a PennCard. 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 AirPennNet, Penn e-mail account and many other essential services. All students are required to have a current, active PennKey and password.

Once admitted into the certificate program, you may receive an email from PennKey with instructions to set up your PennKey. If you have not received this email then please contact [PennKey Support](#).

### Penn Email Address

If you are currently a Penn employee or student, you will not need to set up a Penn email address. If you are not a Penn employee or student, you will need to set up your PennKey before an email address can be requested for you.

For new students, we will email you with your Penn student email address; please do not set one up through any Penn system. Once your Penn email address is sent to you then you will be able to [activate your email address](#), you can use the temporary password sent to you to log into your email account. Then, you can change your password to something you will remember.

For technical email assistance, contact [medhelp@pennteam.upenn.edu](mailto:medhelp@pennteam.upenn.edu), or 215-573-4636.

### Path@Penn

[Path@Penn](#) 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.

### The PennPortal

The PennPortal webpage bundles together links to important information for students. [Access the PennPortal](#) and log in with your PennKey and password.

### Canvas

Canvas is the official learning management system at Penn. All ITMAT Education courses will host course content through Canvas along with course assignments and all communication regarding the course. <http://canvas.upenn.edu>. Support: [canvas@pobox.upenn.edu](mailto:canvas@pobox.upenn.edu).

ITMAT Education Certificates have [a joint Canvas page](#) for all students enrolled in certificate programs. You will see this Canvas community in your Canvas dashboard. Find resources and opportunities there.

## University Resources

Many resources are available to students via the [Graduate Student Center](#) including:

- [New Graduate Student Orientation](#)
- [Wellness at Penn](#)
- [Family Center at Penn](#)
- [Weingarten Learning Resources Center](#)
- [Counseling and Psychological Services \(CAPS\)](#)
- [Penn Career Services](#)
- [Penn Libraries](#)

## University Required Disclosures

Please review the PennBook's [Student-Related Required Disclosures](#).

### Disclosure on Credential Recognition

The ITMAT Education certificate programs (Certificates in Translational Science, Entrepreneurial Science, Regulatory Science, and Regulatory Affairs) are offered by the University of Pennsylvania, an institution of higher education authorized to confer degrees and certificates conferring academic credit under applicable laws of the United States. Students who are interested in participating in the program from countries other than the United States are advised that each jurisdiction may have its own laws and regulations governing online educational programs, and some jurisdictions may not recognize course credit or an online degree awarded by the University as satisfying local requirements for professional licensure, employment qualification, or other purposes. Before enrolling in this program, prospective students should investigate their jurisdiction's treatment of foreign online programs to ensure that participation in this program will meet their objectives.

## Financial Information

### Certificate in Regulatory Affairs

#### Tuition Rates

Certificate tuition is calculated based on course unit tuition plus general and technical fees. Tuition for courses varies by school/department in the summer, and students should contact the individual department to verify tuition cost. Tuition for the Certificate in Regulatory Affairs aligns with the tuition for the Master of Regulatory Affairs program.

Tuition rates for 2022-2023 in the Certificate in Regulatory Affairs can be viewed on the [Master's Program Costs website](#). Scroll down to Regulatory Affairs to view the tuition costs. Financial information related to payment can be viewed on the [financial policies](#) page.

#### Online Services Fee

The online services fee is particular to online programs and enables the University to maintain essential facilities both in person and online such as the library system, museums and institutes, special laboratories, the Student Health Services, online portals and databases, and so on. 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 the course portals and use of email accounts.

### Clinical Fee

Full-time students (enrolled in more than 2 CU 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 and equivalent capitated payment).

A review of the Penn Student Insurance Plan can be found on the [wellness website](#).

\*Tuition & fees refers to Tuition, General Fee, and Technology Fee. Clinical Fee is separate and is only removed when registration is below 3 CU. Clinical Fee will be removed through the Drop Deadline but not afterward.

### ***Health Insurance***

All full-time students enrolled for a semester or more must carry adequate health insurance as a condition of student enrollment. Students who have their own insurance can waive enrollment in the Penn Student Insurance Plan (PSIP) only if their plan meets certain criteria found on the Student Health Service website.

[Information on insurance compliance can be found here.](#)

**Generally, Certificate students will not be full-time, as they take 1-2 CUs per semester and 3 CUs confers full-time status.**

### Tuition Benefits

University of Pennsylvania employees should refer to the [Human Resources Website](#) for specific details about tuition benefits, including tax implications.

University employees who desire (and are eligible) to use tuition benefits must request tuition benefits during each and every semester via the [Online Tuition Management System](#). See benefit request [deadlines](#).

1. Go to the Online Tuition Management System
2. Click Continue, then log in with your PennKey.
3. Click Tuition Benefits Management.
4. Click Tuition Benefits for Myself, on the top left.
5. Request Payment.

Tuition benefits are available for each semester during particular windows. Below are the dates which tuition benefits are available for the 2022-2023 year.

| Semester                                       | System Opens to Requests | Deadline for Submitting Requests |
|--|--------------------------|----------------------------------|
| Spring   | November 1               | March 15                         |
| Summer Session I and<br>12-week Summer Session | April 1                  | June 15                          |
| Summer Session II                              | April 1                  | August 15                        |
| Fall   | June 1                   | November 15                      |

### Billing Information

Once students are registered for courses an electronic bill for the course units will be sent, students are expected to complete payment by the date noted on the bill. The billing schedule details the date bills will be sent and the date bills are due. Visit the [Billing Schedule Website](#) to view the due dates for upcoming semesters. You can access and pay your bill on the [billing payment](#) website. You may also view third party payment plans on the [billing](#) website.

All students are billed per course unit (CU) up to 3 CU. At 3 CU, the Online Services Fee, and Technology Fee are billed at a flat rate and will not increase after 3 CU. Tuition will not be billed at a flat rate.

At 3 CU, a student is considered full-time and is eligible for access to campus recreation spaces. Full-time students will be billed a Clinical Fee each term, which provides access to Student Health Services. Students who are full-time employees—at Penn or elsewhere—and have health insurance through their employer should notify the program so that the Clinical Fee may be removed; Penn employees do not have access to Student Health Services.

During the fall and spring terms, Penn offers a payment plan for students who wish to pay their bills in installments. The Penn Payment Plan is a voluntary, interest-free installment plan designed for students who prefer to spread all or a portion of their educational expenses across multiple payments each semester. To learn more and enroll in the plan, see the [Student Registration and Financial Services website](#).

### Financial Aid Requirements for Satisfactory Academic Progress

If you are using financial aid, then you must meet the following requirements.

- GPA of 3.0 or higher at the end of every term
- The student must be completing credit units at a rate which would enable them to complete the requirements for the degree in a maximum time frame of 150 percent of the published length of the academic program (1.5 years or 4 terms including a summer term).
- The student must successfully complete at least two thirds of courses attempted during their degree program. Marks, such as NR, GR, and I, do not count as completed coursework.

To learn more, visit the [financial aid website](#).

### University Policies for Withdrawal, Refunds, and the Return of Financial Aid

Please review the university policies on:

- [Return of Funds](#)
- [Reduction of Tuition and Fees \(upon withdrawal\)](#)
- [Unofficial Withdrawals](#)

## Certificates in Translational, Entrepreneurial, and Regulatory Science

### Description of Fees

Certificate tuition is calculated based on course unit tuition plus general and technical fees. Tuition for courses varies by school/department in the summer, and students should contact the individual department to verify tuition cost. Tuition for the Certificate in Regulatory Affairs aligns with the tuition for the Master of Regulatory Affairs program.

Tuition rates for 2022-2023 can be viewed on the [Master's Program Costs](#) Website. Scroll down to the Master of Translational Science and/or Regulatory Science and select the plus sign icon to view the tuition costs. Financial information related to payment can be viewed on the [financial policies](#) page.

Billing is as follows:

- Certificate in Translational Science: Billed via Translational Research tuition and fees
- Certificate in Regulatory Science: Billed via Regulatory Science tuition and fees
- Certificate in Entrepreneurial Science: Billed via Translational Research tuition and fees

Note: These programs are not eligible for federal financial aid programs, but tuition benefits are available to qualifying faculty and staff.

### Funding

If your tuition will be supported via a Training Grant (T32, TL1, etc.) or Departmental fund, please contact your ITMAT program administrator in advance of your first tuition bill to learn what information is needed to process tuition payment.

If you have access to third party funding for tuition, please review the [process for setting up a Third Party Payment contract](#).

### 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 the course portals and use of email accounts.

### Clinical Fee

Full-time students (enrolled in more than 2 CU 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 and equivalent capitated payment).

A review of the Penn Student Insurance Plan can be found on the [wellness website](#).

\*Tuition & fees refers to Tuition, General Fee, and Technology Fee. Clinical Fee is separate and is only removed when registration is below 3 CU. Clinical Fee will be removed through the Drop Deadline but not afterward.

***Health Insurance***

All full-time students enrolled for a semester or more must carry adequate health insurance as a condition of student enrollment. Students who have their own insurance can waive enrollment in the Penn Student Insurance Plan (PSIP) only if their plan meets certain criteria found on the Student Health Service website.

[Information on insurance compliance can be found here.](#)