

***Rutgers' School of Health Professions/ Biopharma Educational Initiative***

***MS in Clinical Trial Sciences***

***Regulatory Affairs Certificate***

***Recruitment Sciences Certificate***

***Drug Safety & Pharmacovigilance Certificate***

***Student Handbook***

***2018-2020***

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**This manual identifies policies specifically related to the MS in Clinical Trial Sciences. Please be aware that as a student at SHP, you must be familiar with not only the policies of the program but also the policies of the School of Health Professions (SHP), Rutgers Biomedical and Health Sciences (RBHS), and Rutgers University.**

## **1. Welcome Note**

Welcome to the Biopharma Educational Initiative. The faculty extends a warm welcome and looks forward to mentoring and guiding you into the exciting world of Clinical Trials.

Your experiences at SHP may be somewhat different than your previous academic exposure. First our classes are all online. Web-based education requires more active participation by the student than in a traditional in-person lecture class. The course content is available to you 24 hours a day, 7 days a week, which allows you to review the material at your own pace while juggling family and work responsibilities. Many of the courses have audio lectures and these files may be downloaded to your computer to go with you during your travels. Course content is presented in a manner commensurate with graduate level education and requires significant contributions and participation from the student. The faculty will reinforce the content through guided discussion activities, feedback, and other assignments. Successful students are self-directed learners who strive to understand the material on a conceptual basis rather than just through memorization.

Many of our faculty members are leaders in the pharmaceutical industry. They enjoy teaching and look forward to sharing their experiences with you. You will be treated as a professional and colleague, and we are assured that you will return that respect to your professors.

Please review this student handbook carefully and keep it accessible as you continue through the program.

## **2. Introduction to the Program**

[The Biopharma Educational Initiative](#) is a unique **WEB-BASED** program that brings together New Jersey's biotechnology and pharmaceutical industries with the University in an academic partnership to develop career enhancing educational opportunities for existing or future biopharmaceutical employees. Bringing to market new drugs and devices has become a complex process requiring the skills of specialized and talented clinical research professionals. Through both post-baccalaureate certificates, and a Master's Degree Program we educate individuals to become "Clinical Research Professionals" who possess a thorough understanding of clinical trials, research design, ethics, national and international regulatory processes, and clinical trial monitoring. Clinical Scientists utilize these knowledge areas to monitor the conduct and progress of trials either in the US or globally.

The Biopharma Educational Initiative sits in the heart of "Pharma Alley" in New Jersey. Because of this proximity to both large and small pharmaceutical and biotech companies we have been able to add individuals who are among the brightest and most talented Pharma employee professionals to our already impressive coterie of University faculty. In addition, we are one of the largest health care research institutions in the US with our own contract research organization and well-regarded research facilities. Networking with industry leaders and gifted principal investigators are valuable assets

offered to our students. Enrollment is available within our Master's specialization tracks or our three Certificate Programs, and also to applicants seeking only visiting student enrollment in individual courses. These web-based courses were designed to fit into the busy schedules of working professionals.

The Biopharma Program provides education to those individuals who seek to gain expertise or advanced job skills in such fields as a Regulatory Affairs, Clinical Research Monitoring, Drug Safety & Pharmacovigilance or Medical Affairs, within the pharmaceutical industry. We offer a Masters Degree in Clinical Trial Sciences as well as three graduate level certificates; Regulatory Affairs, Recruitment Sciences, and Drug Safety and Pharmacovigilance. The Masters degree is 36 credits, with a 9-credit core and 27 credits of specialty courses and electives. Students can choose one of four tracks for specialization (see below). Each certificate is 5 courses/15 credits in length.

### ***3. Specialization Tracks***

#### ***Clinical Trials Management & Recruitment Sciences***

This specialization track presents the knowledge and skills necessary for effective clinical trial management from the sponsors' perspective as well as that of the individual study sites. Protocol development, IRB submissions, managing study budgets, facilitating proper data collection, and preparing for a study audit, conducted in an ethical manner are all essential skill sets required of persons working in clinical research. In addition, students in this track will be on the forefront of developing strategies for a new and growing pharma job role, the Patient Recruitment Specialist.

#### ***Regulatory Affairs***

The laws and guidelines that regulate the research, marketing approval, manufacturing and advertising of drugs, biologics, and medical devices are often complex and change frequently. Several new recommendations submitted to Congress may significantly broaden the Food and Drug Administration's ability to monitor the safety of drugs and devices and to improve the agency's ability to respond to emergent drug and device safety issues. The material offered in this track prepares the student to conduct essential filings with regulatory agencies and to have a thorough understanding of law, policy, and business governing bringing product to market.

#### ***Drug Safety & Pharmacovigilance***

There is a risk: benefit ratio for every drug, biologic and medical device. Some of the risks are known early in the development phase and can be predicted by pre-clinical studies. However many safety issues first come to light only after large-scale clinical trials are conducted in the post-marketing phase of development. Some issues are related to a drug's mechanism of action but others may be related to manufacturing issues or problems with product labeling and information leaflets. As drug recalls grow there has been a greater emphasis put on identifying signals both in the clinical phase of study and after the product has been released on the market.

This specialization track educates the students on how to recognize, quantify, analyze, and communicate the benefits and risks associated with drug and related products. The Certificate in Drug Safety and Pharmacovigilance will have a similar goal but will be primarily intended for the student currently working within the profession or for the student who wishes to pursue work on the regulatory aspects of pharmacovigilance and not signal detection.

### ***Medical Affairs***

This specialization track teaches the knowledge and skills necessary to enter various facets of medical affairs which is a high growth area in the biopharmaceutical industry. Positions in this area are necessary to manage the growing vital sector in today's industry in providing key opinion leaders, regulatory agencies and healthcare professionals with scientific and medical information relating to the value and correct usage of the products. Medical affairs personnel strive for the highest scientific integrity so as to produce successful clinical trials and supply the greatest support for the market. Medical affairs groups perform many activities often overlapping with sales, Medical marketing, clinical growth, and customer service. In parallel, they serve as the bridge between the company's internal stakeholders, especially clinical development and the company's external stakeholders. Medical Affairs' focus on generating meaningful evidence, strategic engagement of key opinion leaders and the dissemination of relevant scientific information makes it paramount for them to ensure their knowledge and skills are well supported by a formidable education system.

This specialization track educates the student on the role of medical affairs in commercialization, in particular, to develop research hypotheses and designs for medical affairs studies, disseminate study results in an effective and efficient way to various stakeholders, design communication strategies, develop brand strategies, understand stakeholder needs (e.g., regulatory affairs, market access) and develop strategies for win-win partnerships, address challenges that medical affairs faces in commercialization, and interpret regulatory and clinical guidelines.

### ***4. History of the Program***

The Biopharma Educational Initiative was designed as an Industry and University collaboration to develop academic programs and courses to meet the needs of the biopharmaceutical industry and their employees. During the Academic Year 2004-05, University-wide meetings were held to discuss greater collaboration with the pharmaceutical industry. The primary focus was to develop a curriculum and appropriate academic programs centering on clinical trials. In the summer of 2005, the University identified resources to establish an administrative office to deal with infrastructure considerations. The office was charged with developing appropriate committees to deal with various academic, faculty and student issues as well as the development of requisite administrative policies and processes. Since the University is made up of numerous and diverse schools, both in terms of instructional content and governing policies, attempts to develop a blend of policies, grading scales, and

admission and registration policies was a challenge. The School of Health Professions took the lead in this effort by creating a Director of Admissions & Registration for Corporate Education and a Director of Curriculum Development. Fees, admissions policies, grading scales were coalesced, and one portal of entry into the University was created to obviate students having to apply to each of the schools individually. In addition, interested faculty from the various schools developed new or modified existing courses for on-line presentation.

In 2004 we were approached by Merck & Co. to develop our first academic certificate in Clinical Recruitment Sciences. This was established secondary to the need to provide graduate level education for a new job title in the biopharmaceutical industry entitled "Patient Recruitment Specialist". Subsequently, other companies have asked for graduate courses in clinical data management and regulatory affairs and hence served as the impetus for development of two other certificates, Clinical Trials Informatics (which has since been eliminated) and Regulatory Affairs. These 15 credit (5 courses) certificates were then phased in starting in the Fall of 2006.

Due to the complexities involved in running a clinical trial both in the US and abroad, it quickly became apparent that a 5 course curriculum did not offer the depth and breadth of information needed by the Clinical Research Professional. Hence in the Spring of 2008 we began putting together a Masters degree in Clinical Trial Sciences with finalization and approval from New Jersey's Commission on Higher Education obtained in March of 2009.

## **5. Program Governance**

As mentioned earlier, the Biopharma Educational Initiative is a collaborative effort. The certificates are University certificates and thus awarded by the school directly involved in the students' course of study; however, a degree program (meaning a MS or PhD) must be awarded through a school. Since Biopharma is technically not a school, it cannot award a degree; hence the Masters is awarded through the School of Health Professions. This technicality, however, has led to possible confusion in the application process.

Students applying to the Masters Degree in Clinical Trial Sciences must use the [SHP application](#) and their paperwork and supporting documents are processed through the [SHP Enrollment Services Office](#). Once accepted, students will register for courses through the [Banner Information System](#).

Students applying to the Certificate programs, as well as students registering for individual courses on a non-matriculated basis must use the [CACE Application for Certificate of Studies](#) and their paperwork and supporting documents are processed through the [SHP Enrollment Services Office](#). Once accepted, students will register for courses using the [Non-Matriculated Course Enrollment Form](#).

## **Program Administrative Staff and Faculty**

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### **6. Program Goals**

The goals and objectives of the program vary depending on track chosen but all students will be able to describe the drug development process, identify/edit elements of a protocol, and explain a variety of research designs. They will learn to apply ethical principles to the development and conduct of clinical trials, interpret and summarize major regulatory documents in the U.S. and compare and contrast these with international regulations. Students will understand how to provide safe, competent clinical care to the participants in clinical trials.

### **7. Program Competencies**

#### **Core Competencies**

- Formulate a basic study design incorporating knowledge on sample size, placebo response, significance, blinding, minimizing bias, randomization, as well as concepts surrounding multiple analyses and multiple treatment arms and endpoints;
- Select and utilize appropriate software for data entry, tracking recruitment, and managing the budget and expenditures for study managers;
- Improve research designs and epidemiological studies, and identify how changes in health policy and economics influence study design;
- Critique the drug literature with regard to study design, methods, statistics, quality of literature review, conclusions, and writing style and organization;
- Apply ethical principles to the development and conduct of clinical trials, including informed consent and subject recruitment and retention, and identify cases of error, misconduct and fraud;
- Interpret and summarize major regulatory documents in the U.S. and compare and contrast these with international regulations;

- Assess adverse effects by utilizing several methods including severity scales, toxicity criteria, and similar response variables, and document the event for the sponsor, appropriate regulatory agencies, and in the literature;
- Explain the drug/device/biologic evaluation process including all phases of product development in clinical research and GCP guidelines impact on quality
- Disseminate study results in the form of reports to regulatory agencies, to the sponsor and contributions to publications in medical journals;
- Construct plans for training investigators and/or study staff to promote standardization of study procedures;
- Discuss principles of pharmaceutical project management and identify components of the project strategy (target product profile, business strategy, clinical strategy, regulatory strategy, financial analysis);
- Identify important clinical questions to develop a research hypothesis;
- Learn how to provide safe, competent clinical care to the participants in clinical trials.

### ***Regulatory Affairs Competencies***

- Develop and submit applications for permission to study and market products to a variety of international and national regulatory agencies;
- Interpret regulations involved in the investigation, production, labeling and distribution of drugs, food, additives, medical devices, biological products, pesticides and other similar products, and provide guidance on these rules to the project team;
- Assist in protocol development to satisfy new requirements for post-marketing commitment studies;
- Understand the various regulatory documents involved in pharmacovigilance
- Develop Regulatory Strategies that enable the launch of drugs in foreign markets
- Identifying concepts involved with GXP as it relates to Good Manufacturing Practices (GMP), Good Clinical Practices (GCPs) and Good Laboratory Practices (GLPs); Outline the steps in a preventive action investigation by documenting the background of the issue and to identify a corrective action to the deviation and a suggested timeline of completion

### ***Clinical Trials Management & Recruitment Competencies***

- Demonstrate knowledge of pathophysiology and pharmacology;
- Interpret the appropriate portion of the CFR and use this document to guide the execution of Clinical Research professional;
- Conduct study specific activities for a study and conduct protocol feasibility such as preparing case report forms/electronic data capture, storage of study materials and documents, informed consent documents, as well as budget, close-out procedures and perform post study analysis;
- Design and monitor recruitment campaigns with an understanding of influences such as disease, pharmacogenomics, culture and religion;
- Research and test methodologies used for patient recruitment to develop

- evidence based approaches to this study area;
- Formulate a business plan for a clinical trial including managing external funding, budgeting processes, cost-benefit and cost-effectiveness data;
- Demonstrate a working knowledge of databases used to capture outcomes, biomarkers, and endpoints from the site investigators.
- Design a quality assurance plan to coincide with study initiation procedures

### ***Drug Safety & Pharmacovigilance Competencies***

- Analyze differences in safety regulations/guidances between different global regions
- Analyze adverse events based on seriousness and labeledness/ expectedness
- Prepare drug safety narrative
- Describe the key drug safety reporting requirements that must be filed with a regulatory agency
- Outline traditional and statistical data mining methods
- Perform risk identification (signal detection) and characterize identified risks, potential risks based on signal analysis to develop a risk management plan
- Identify the different Risk Management Tools such as RMPS and REMS
- Review published literature of clinical and preclinical reports to provide a framework to judge adverse events
- Describe databases containing adverse drug events, such as MedDRA and Eudravigilance and explain how they are used.
- Identify major drug induced adverse events or safety signals and the rationale for their development

### ***Medical Affairs***

- Demonstrate scientific and technological thought leadership to enable to think across therapeutic areas, assess critical value, analyze risk versus benefit and exploit technological advances
- Demonstrate a deep understanding of compliance in order to appreciate the options and constraints of an increasingly compliance driven environment
- Develop emotional intelligence and communication skills to understand and engage customers and colleagues
- Formulate and Implement strategies to partner with commercial and development colleagues and engage in lifecycle planning; understand the changing customer landscape
- Demonstrate business leadership to partner with commercial and development colleagues and engage in lifecycle planning; understand the changing customer landscape
- Apply and demonstrate learning agility to take current knowledge and adapt it for future use both within and outside the core medical capability

## ***8. Sample Curriculum for Master of Science Programs***

The following is a ***sample curriculum*** based on taking two courses/semester:

<b>Semester/ Year</b>	<b>Regulatory Affairs</b>	<b>Clinical Trial Management &amp; Recruitment</b>	<b>Drug Safety</b>	<b>Medical Affairs</b>
<b>Fall/ Year 1</b>	Regulatory Requirements in Clinical Investigations  Adverse Event Reporting & Postmarketing Activities	Regulatory Requirements in Clinical Investigations  Overview of Disease Processes and Treatment	Regulatory Requirements in Clinical Investigations  Overview of Disease Process & Treatment**	Clinical Trials Overview: Methods and Practice  Overview of Disease Processes and Treatment
<b>Spring/ Year 1</b>	Clinical Trials Overview: Methods and Practice  Data Analysis and Interpretation or Multiple Analyses in Clinical Trials	Clinical Trials Overview: Methods and Practice  Multiple Analyses in Clinical Trials or Data Analysis and Interpretation	Clinical Trials Overview: Methods and Practice  Adverse Events	Regulatory and Ethical Requirements in Clinical Investigation  Applied Clinical Trials and GCP
<b>Summer/ Year 1 (Mandatory for Medical Affairs)</b>				Advertising & Labelling in Pharmaceutical Medicine  Strategy, Insight Generation and Patient Journey
<b>Fall/ Year 2</b>	International Regulatory Affairs  Concepts of GxPs & Quality Assurance	Clinical Operations  Biomedical Informatics in Clinical Trial Management	Risk Management Tools  Pharmacoepidemiology	International Regulatory Affairs  Scientific Writing for Translation for Medicine
<b>Spring/ Year 2</b>	Elective  Elective	Applied Clinical Trials & GCP  Elective	Principles Of Pharmacovigilance  Data Analysis and Interpretation or Multiple Analyses in Clinical Trials	Elective  Special Topics in Clinical Trial Sciences
<b>Summer / Year 2 (Mandatory for Medical Affairs)</b>				Capstone  The Practice of Medical Affairs
<b>Fall/ Year 3</b>	Regulatory Requirements for Medical	Elective  Elective	Signal Detection & Quantifying Risk	

	Devices/Diagnostics Elective		Elective	
<b>Spring /Year 3</b>	Regulatory Writing for Submissions & Publication  Capstone Course (or Evidence Based Literature Review or Scientific Writing for Translation for Medicine)	Principles of Subject Recruitment and Retention  Capstone Course (or Evidence Based Literature Review or Scientific Writing for Translation for Medicine)	Clinical Pharmacology  Capstone Course (or Evidence Based Literature Review or Scientific Writing for Translation for Medicine)	

**\*\*Physicians/PharmDs/Nurses may replace this course with an elective or a course from one of the other tracks.**

### **9. Graduate Certificate Program**

The Biopharma Educational Initiative offers three, 15 credit online certificates: Certificate in Recruitment Sciences, Certificate in Regulatory Affairs, and Certificate in Drug Safety & Pharmacovigilance. The Requirements for Graduation (RG) for each certificate are listed below.

#### ***Certificate in Clinical Trials Recruitment Sciences***

<b>COURSE CODE</b>	<b>TITLE</b>	<b>CREDITS</b>
<b>Core-Required</b>		
BPHE 5510P	Overview of Disease Processes and Treatment	3
BPHE 5521P	Regulatory and Ethical Requirements in Clinical Investigation	3
BPHE 6985P	Principles of Subject Recruitment and Retention	3
<b>Electives - Choose Two</b>		
BINF 5075E	Medical Bioinformatics for Clinical Trial Management	3
BPHE 6352P	Applied Clinical Trials	3
BPHE 6510P	Clinical Operations	3
	Courses from other Specialization Tracks may be taken as an elective	
	<b>Total</b>	<b>15</b>

#### ***Certificate in Regulatory Affairs***

<b>COURSE CODE</b>	<b>TITLE</b>	<b>CREDITS</b>
<b>Core-Required</b>		
BPHE 5310P	Clinical Trials Overview: Methods and Process	3
BPHE 5521P	Regulatory & Ethical Requirements in Clinical Investigation	3
BPHE 5725P	Adverse Event Reporting & Postmarketing Activities	3
<b>Electives - Choose Two</b>		
BPHE 5110P	Food and Drug Law	3
BPHE 6200P	Concepts of GxPs and Quality Assurance	3
BPHE 6530P	International Regulatory Affairs	3
BPHE 6600P	Advertising & Labeling in Marketing Pharmaceuticals	3
BPHE 6500P	Regulatory Requirements for Medical Devices	3

BPHE 6800P	Regulatory Writing for Submission & Publication	3
	Courses from other Specialization Tracks may be taken as an elective	
	<b>Total</b>	<b>15</b>

### ***Certificate in Drug Safety & Pharmacovigilance***

<b>COURSE CODE</b>	<b>TITLE</b>	<b>CREDITS</b>
<b>Core-Required</b>		
BPHE 5521P	Regulatory & Ethical Requirements in Clinical Investigation	3
BPHE 5725P	Adverse Event Reporting & Postmarketing Activities	3
BPHE 5780P	Principles of Pharmacovigilance, Regulations & Drug Safety Reporting	3
<b>Electives - Choose Two</b>		
BPHE 5510P	Overview of Disease Processes and Treatment	3
BPHE 6000P	Risk Management Tools	3
BPHE 7510P	Clinical Pharmacology	3
BPHE 7600P	Analyzing Clinical Data To Determine Adverse Events	3
BPHE 5750	Six Sigma Methodology	
	<b>Total</b>	<b>15</b>

### **10. Academic Policies**

The [School of Health Professions Student Handbook](#) and [Rutgers Biomedical and Health Sciences Policies](#) contain policies to which the Clinical Trials Sciences MS and Certificate students are to follow. This Handbook includes highlights of some of these reference policies, as well as information about specific Biopharma Educational Initiative policies that provide supplemental information to SHP policies. You need to be aware of all of these policies.

### **11. Program Admission Policies (companion to SHP Student Handbook Policy 1.0)**

Applicants to the MS in Clinical Trial Sciences must possess a minimum of a Bachelor's Degree and a GPA of 3.0. Additionally, applicants must submit a "Goal Statement" and two letters of recommendation to the [Office of Enrollment Services](#). Applicants to any of the Certificate Programs must submit the same documentation as applicants to the MS degree program with the exception that only one letter of recommendation is needed.

### **12. Transferring from a Certificate Program to the MS in Clinical Trial Sciences (companion to SHP Student Handbook Policy 1.1.5)**

Students wishing to transfer to the MS program from a certificate or non-matriculated status must re-apply using the SHP Application Form. The student will also be required to submit the application fee and one additional letter of recommendation. Students must be in good academic standing with an overall GPA of 3.0 or above. All Biopharma certificate courses with a grade of "B" or higher can be accepted into the Masters Degree and appropriate advanced standing may be given to the student.

**13. Readmission to the Program (companion to SHP Student Handbook, Policy 1.4.1)**

Students who withdraw either officially or unofficially from the program may reapply for readmission. The application will be considered along with all newly applying students and judged on its merits.

Students who are accepted into the program may request a deferment for up to one year. The Deferment Form may be found on the SHP website under Enrollment Services.

**14. Student Enrollment Status** (companion to SHP Student Handbook Policies 2.0, 2.0.1, 2.0.3 and 2.0.4)

Students are expected to attend classes in consecutive semesters (except for summer, unless the student is in the Medical Affairs Track where Summer term is mandatory). If a student needs to step out of the program for a semester or longer, they must complete appropriate documentation that describes the purpose and nature of the change in enrollment status.

**Categories for change of student status include:**

**--Maintaining Matriculation:** Status while working on an incomplete or awaiting graduation

**--Leave of Absence:** Student may request to step out of the program for up to one year due to extenuating circumstances. Program approval required.

**--Withdrawal from Program:** Student wishes to withdraw from the program.

Failure to complete and submit appropriate documentation may result in disenrollment from the program. It may also necessitate a filling of a new program application, as well as an application fee.

If you are a Masters student, please complete the [SHP Maintaining Matriculation/Leave of Absence Form](#) and return to Office of Enrollment Services, 65 Bergen Street, Room 149, Newark, NJ 07107-1709 or Fax to (973) 972-7463, email: [sn\\_shp\\_registrar@ca.rutgers.edu](mailto:sn_shp_registrar@ca.rutgers.edu).

If you are a Certificate student, you must fill out the Biopharma Educational Initiative [Change of Student Program Status Form](#) and submit the completed form to the Program Director, Biopharma Educational Initiative (e-mail: [lechnedw@shp.rutgers.edu](mailto:lechnedw@shp.rutgers.edu))

Students wishing to withdraw from a program and school must consult with the Program Director, complete the “Program Withdrawal and Course Withdrawal Form”, and submit this information to the Office of Enrollment Services, 65 Bergen Street Room 149, Newark NJ, email: [sn\\_shp\\_registrar@ca.rutgers.edu](mailto:sn_shp_registrar@ca.rutgers.edu). The form will be forwarded by the Registration office to your program for approval.

An administrative fee may be assessed for a change in status. Students who return from an approved leave of absence are not required to reapply to the program. Re-enrollment however must be arranged through Enrollment Services for the MS students and through the Program Director for the Certificates. Students seeking to continue on leave status must notify Enrollment Services and the Program Director for the Biopharma and indicate an expected return date.

#### ***15. Leave of Absence (companion to SHP Student Handbook, Policy 2.0.2)***

The Biopharma Educational Initiative follows the SHP Leave of Absence Policy. Students may take a leave of absence up to one year at a time. Taking two LOA's back to back is prohibited.

#### ***16. Taking Courses on a Non-Matriculated Basis (companion to SHP Student Handbook Policy 2.3)***

Students may take up to 12 credits on a non-matriculated basis before an application is required to either a certificate program or the MS degree. If students do not register for a course after one year they will become inactive and need to re-enroll.

#### ***17. Immunization Policies***

Since the MS and Certification programs in Clinical Trial Sciences are online programs, no specific immunizations are required. However they may be needed prior to participating in a mentored fieldwork experience. Please check with the fieldwork site to determine if immunizations are necessary.

#### ***18. Transfer Credit (companion to SHP Student Handbook Policy 2.5)***

The Biopharma Educational Initiative may accept in transfer a maximum of 9 credits in the MS program. Credits must be recently earned (within 5 years) at the designated academic level. Courses/credits must appear on an official academic transcripts from previously attended U.S. colleges, universities and other post-secondary accredited institutions. Such institutions must be approved or accredited by agencies recognized by the Council on Postsecondary Accreditation (e.g. Middle States Association of Colleges and Schools, American Medical Association Commission on Accreditation of Allied Health Educational Programs, American Dental Association Council on Dental Accreditation, American Council on Education, National League of Nursing) or other appropriate program accrediting agencies. **Transfer credit will be accepted only**

**when admitted to a degree program.** No transfer credit will be accepted for a student entering a Biopharma Educational Initiative Certificate program

Only graduate credits with a grade of “B” or better or equivalent (3.0) shall be considered for acceptance. Transfer credits may also be awarded for courses completed in institutions in foreign countries, provided acceptable evaluation of the course work is documented by agencies approved by the University. Advanced standing may be granted following review and evaluation by appropriate faculty. Additionally, transfer credits must be related to the program of study under the Biopharma Educational Initiative.

A student cannot receive two degrees simultaneously using the same course work to fulfill the course requirements for both. In addition, a student cannot be registered for two tracks at the same time. If a student wishes to obtain a second degree, he/she must apply to the program and then transfer only authorized credits consistent with the policy as stated above. Transfer course work is defined as those courses taken prior to enrollment that are determined to be equivalent to specific courses that are required for graduation.

Once a [Transfer Credit Form](#), is approved by the Program Director and Dean Designee, it will then be forwarded to Enrollment Services for processing. Once Transfer Credit has been entered, it will appear on your official transcript and viewed through your [University Portal](#).

### ***19. Registration- Portfolio Assessment (companion to SHP Student Handbook Policy 2.5.1)***

Portfolio Assessment is used to grant credits for knowledge and skills obtained outside the usual academic venue. This option is available only to new incoming MS students. A formal request for a portfolio review must be submitted to the Director once the student has returned their acceptance letter. A portfolio fee will be assessed at ½ the tuition for the course. Advanced standing and credit may be granted to an MS student. A certificate student may be given an allowed exemption from a particular course but the student will still need to register for another course in its place.

### ***20. Registration- Credit by Examination (companion to SHP Student Handbook Policy 2.6)***

Students wishing to sit for an exam to waive or place out of a course must submit in writing a request a minimum of 8 weeks prior to the start date for the course. Permission may be granted by the Director and Dean or Dean Designee. This option is available only to students who have taken similar course work at another institution and whose credits are older than 8 years. Students must be able to document school work covered by the course and the exam must be completed prior to the start of the semester in which the course is offered. Students passing the exam with a “B” or better

will receive a performance grade and credits for the course. The regular tuition rate is charged for credit by exam.

## **21. Grading System Policy (companion to SHP Student Handbook Policy 3.0)**

### **Grading Scale:**

Grade	Graduate Scale	Quality Points
A	93.0-100	4.0
A-	90.0-92.9	3.7
B+	87.0-89.9	3.3
B	83.0-86.9	3.0
B-	80.0-82.9	2.7
C+	77-79.9	2.3
C	73.0-76.9	2.0
C-	70.0-72.9	1.7
D+	67.0-69.9	1.3
D	63.0-66.9	1.0
F	<63	0.0

### **IP - In Progress**

The provisional grade of "IP" (in progress) is assigned to courses that extend more than one semester. An IP can also be issued for the Capstone Course when the start date has been postponed due to contract delays. The Capstone Course must be completed within the sequential semester that it was started.

### **I-Incomplete**

A grade of "I" is given only when circumstances such as student illness, injury, family crisis or an unavoidable absence from class such as military service, prevent completion of course requirements. The instructor retain the right to award the "I" when the following criteria has been met:

- The Withdrawal period is over. If the course extends over two semesters, the In complete may be given following the withdrawal period for the second semester.
- The student's performance is satisfactory, with a grade of "B- or better for graduate students. Under no circumstances will an Incomplete be given as a substitute for a failing grade. The incomplete must be converted to a performance grade before the end of the next semester in which the "I" was received, or sooner, at the discretion of the Instructor. However, the length of time should be based on whether the work missed requires interaction with other

students, necessitating that the student wait for the next course offering, or complete the missing work independently.

## ***22. Eligibility for Fieldwork Experience (companion to SHP Student Handbook Policy 3.1)***

To be eligible, students must have earned a "B-" or better in ALL courses while enrolled in the program. Even if a course has been repeated and a higher grade earned, the lower grade will preclude eligibility for this opportunity. In addition, students must have demonstrated high ethical performance during their course work. Students who have breached the Honor Code, Academic Integrity, or displayed any other "Acts of Misconduct" will also not be eligible for fieldwork.

## ***23. Completion of Work (companion to SHP Student Handbook Policy 3.1)***

Students who are late in submitting assignments or taking quizzes will be penalized 2 points per day for every day they are late unless prior arrangements have been made with the instructor or legitimate extenuating circumstances occur (see above section for documentation of these circumstances). The instructor reserves the right to request documentation on a case by case basis. For late submission of Discussion posts, please see the grading rubric in each syllabi.

Students enrolled in our program need to understand that education beyond the high school and undergraduate level goes beyond just reading and summarizing of text. Our program expectation involves reading from a variety of sources, critically thinking and analyzing the information and then integrating the material to answer a question, prepare an argument, develop a new theory or idea, or compare or contrast differing opinions or facts. The discussion board and voice threads in Moodle are often a platform for this type of analysis. Utilizing quotations in these forums will not be tolerated since it is our view that they should only be from experts, and ONLY be used in cases in which paraphrasing would cause a loss of meaning or effect. If quotations are used in a research paper, the student should explain why these quotes were used.

## ***24. Academic Decision and Grade Review***

The Biopharma Educational Initiative follows the SHP policy for Academic Standing and Grade Review (SHP policy #3.1.1).

## ***25. Satisfactory Academic Progress/Minimum Grade Point Average/Length of Program/Probation (companion to SHP Student Handbook Policy 3.1.2)***

All students enrolled in either the certificate or masters programs must maintain an overall GPA of 3.0.

If a certificate student's overall GPA drops below 3.0, he/she will not be able to receive the certificate until they raise their overall GPA to that level. This may necessitate taking additional courses above the required five in order to raise the GPA. There is no probation for certificate students.

In the Masters program students with GPA's less than 3.0 will be placed on probation. Probation is assigned under the following conditions:

1. A grade earned that is less than a C- in any course; or
2. Cumulative GPA < 3.0

If a Masters program student fails to reach a cumulative GPA of at least 3.0 by the end of the next semester or earns another grade below a C-, he/she will be dismissed from the program. Only one probationary period is allowed. Any student who previously received probation must continue to earn at least a B- in all remaining courses or be dismissed. If a student receives a grade of "F" they will not receive credit for that course.

Students enrolled in the MS program will have up to 5 years in which to complete the degree starting from their first semester of enrollment. Students enrolled in any of the Certificate programs will have 3 years in which to complete their studies.

Students are expected to be enrolled in every Fall and Spring semester while matriculated unless a leave of absence is requested and approved. They must complete a [Leave of Absence/Maintaining Matriculation Form](#) for the Masters students and a [BEI Change of Student Program Form](#) for the Certificate students for approval. Failure to do so may result in disenrollment from the program. A fee will be charged for change in program status.

### **26. Academic Warning (companion to SHP Student Handbook Policy 3.1.3)**

If any student is in danger of earning below a "B-" the student will be notified in writing by the Program Director. This warning will outline the problem and offer strategies for improvement. A copy of this communication will be placed in the student's file.

### **27. Probation/ Suspension**

The MS in Clinical Trial Sciences follows the SHP policy for Probation/Suspension (SHP policy #3.1.4).

### **28. Repetition of a Course/Remediation of Unsatisfactory Performance**

The Biopharma Educational Initiative follows the SHP policy for Repetition of Course and Remediation of Unsatisfactory Performance (SHP policy #3.1.5).

### **29. Examination Policy (companion to SHP Student Handbook Policy 3.2)**

It is school policy that a student be present for all scheduled exams (e.g., mid-term and final exams). A student missing an exam will receive an automatic failure unless the absence is due to an illness or emergency that has been documented by a physician or other suitable evidence. In those cases where an exam is missed based on a documented illness or emergency, a student may be permitted to make up the exam. Arrangements to make up the exam must be completed within two weeks after the student's return to class, or at the discretion and instructions of the course instructor.

Repeat exams are at the discretion of the instructor. However, a student will not receive a grade higher than the minimal passing grade or the grade (i.e., B- or 80 grade points).

### **30. Completion of Graduation Requirements**

The Biopharma Educational Initiative follows the SHP policy for Completion of Graduation Requirements (SHP policy # 3.3).

### **31. Student Rights and Responsibilities**

The Biopharma Educational Initiative follows the SHP policy for Students Rights and Responsibilities (SHP policies # 6.1, 6.2, 6.3, 6.4).

### **32. Student Honor Code and Academic Integrity Responsibility (companion to SHP Student Handbook Policy 6.5)**

The faculty of SHP and the Biopharma Initiative believe that both faculty and students must observe and practice high standards of honesty and integrity. Everyone must follow the SHP Honor Code and participate in the Code of Academic Integrity. Plagiarism either in written assignments or in online discussions will not be tolerated. Copying exact words by cutting and pasting text from other sources without proper citing is plagiarism. If you must use the exact words from another source, you must put it in quotes and list the author.

All students must complete the short [Academic Integrity Course](#) as a requirement of admission into our Program and the SHP. This training consists of three short web modules with a pre-test and post-test. These modules review proper citing of references, plagiarism, and other topics related to honesty in academia and research.

Students are also required to comply with the Code of Student Behavior listed in the SHP Student Handbook.

**Violations of the Academic Integrity will be considered with grave concern and may be sanctioned with suspension or dismissal from the program.** Examples of violation include plagiarism, copying another student's work and handing it in as one's

own, unauthorized use of materials (textbook, articles, internet sources) during an examination, and allowing another student to copy your work.

For the full honor code policy, see Appendix A

### **33. Student Disciplinary Procedures**

The Biopharma Educational Initiative follows the SHP policy for Student Disciplinary Procedures (SHP policy #6.5.2).

### **34. Attendance (companion to SHP Student Handbook Policy 6.6)**

Students are expected to meet all requirements for each course including participation in the discussion forum.

Students are expected to contribute to the course and meet all deadlines. If you are unable to participate in class (log on) for one week or more, it is your responsibility to contact the course instructor for notification of your absence (by e-mail or phone). It is also your responsibility to make the necessary arrangements with the appropriate faculty member to make up work due to an absence. An excuse “after the fact” will not be tolerated unless there are special circumstances that could not be avoided.

The instructor shall determine if a make-up discussion question is warranted. Depending on the student’s reasons for the absence, a written notice from the student’s physician may be requested. Failure to participate in the discussion without notifying the instructor will result in a zero grade for that assignment.

Failure to participate in three consecutive modules without notifying the Instructor, or unexcused absence, will result in an unofficial Withdrawal from a course. Students, who unofficially withdraw from a course prior to completion of  $\frac{3}{4}$  of the course, will receive a WF on their transcript. Unofficial withdrawal after  $\frac{3}{4}$  of the course is completed will result in a performance grade as determined by the course instructor. Enrollment Services or the Director of Admissions and Registration will notify students via certified mail when this occurs. If the student notifies the school that they intend on continuing in the course, the matter will be referred to the Director.

Students are responsible for immediately notifying the appropriate School office of any special circumstances that may influence their performance, such as changes in health status and or personal difficulties or disabilities. Students, who do not notify the School promptly, of changes or difficulties, may not request review of academic decisions on the basis of such circumstances.

### **35. Services for Students with Disabilities**

The Biopharma Educational Initiative follows the SHP policy for Services for Students with Disabilities (SHP policy #6.8).

**36. Ethical Statement on Patient Care Responsibility**

The Biopharma Educational Initiative follows the SHP policy for Ethical Statement on Patient Care Responsibility (SHP policy #6.9).

**37. Student Use of Personally Owned Mobile Communication Devices/Recording Devices**

The Biopharma Educational Initiative follows the RBHS policy for Student Use of Personally Owned Mobile Communication Devices/Recording Devices.

**38. Student Essential Functions**

The Biopharma Educational Initiative follows the RBHS policy for [Student Essential Functions](#).

**39. Statement on Professional Behavior and Academic Integrity**

The Biopharma Educational Initiative follows the SHP policy for Statement on Professional Behavior and Academic Integrity.

**40. Student Mental Health Care Services**

The Biopharma Educational Initiative follows the SHP policy for [Student Mental Health Care Services](#) .

**Appendix A: Student Honor Code/Academic Integrity (SHP Student Handbook Policy 6.5)**

**WHEREAS:** The faculty of the University's -School of Health Professions believe health care professionals must observe high standards of honesty and integrity; and

**WHEREAS:** As future health care professionals holding a public trust and as members of the SHP academic community, students must also observe high standards of honesty and integrity in all aspects of education, practice and research; and

**WHEREAS:** Observance of this Code is essential due to the sensitivity and confidentiality required in professional education and practice and because it is required to uphold and promote the public trust, the integrity of the professions represented at SHP and the principles of learning and acquisition of knowledge; and

**WHEREAS:** The faculty and students must make diligent efforts to ensure these high standards are upheld by their colleagues and peers as well as themselves; and

**WHEREAS:** It follows that faculty and students accept responsibility to help ensure that these standards are maintained in SHRP by reporting incidents of academic and professional dishonesty in others;

**THEREFORE:** The faculty and students agree to abide by this Honor Code of the School of Health Professions as follows:

**GENERAL PRINCIPLES AND RESPONSIBILITIES**

The principles of truthfulness, fairness, respect for others, trust, and responsibility and a personal commitment to maintaining these high standards and values constitute the fundamental ideal we all must strive to attain. Accordingly, SHP faculty and students have the following responsibilities:

- To be truthful in all academic and professional matters, and to always honestly represent their work and that of others;
- To be aware of and to abide by all applicable federal, state and local civil and criminal laws and regulations;
- To be aware of and abide by all applicable codes and standards of ethical and professional conduct and responsibilities, including those established by the profession in which the student's course of study is intended to prepare him or

her to practice;

- To be aware of and to abide by all applicable University and school policies, rules, procedures and standards, both general and academic; and the responsibility for personal and professional integrity and honesty in all academic activities;
- To help ensure that high standards of professional and ethical conduct are upheld by faculty, students, colleagues and peers by reporting violations of this Honor Code observed in others to the appropriate School official.

Violations of this Honor Code include conduct that does not fully comport with the statements and principles above. Examples of violations include, but are not limited to, conduct listed below.

### **EXAMPLES OF VIOLATIONS OF ACADEMIC INTEGRITY AND OF STANDARDS OF BEHAVIOR**

**CHEATING** occurs when an individual misrepresents his/her mastery of the subject matter or assists another to do the same. Instances of cheating include, but are not limited to:

1. Copying another's work and submitting it as one's own on an examination, paper or other assignment;
2. Allowing another to copy one's work;
3. Using unauthorized materials during an examination or evaluation such as a textbook, notebook, or prepared materials or possession of unauthorized materials (notes, formulas, etc.) that are visually or audibly accessible.
4. Collaborating with another individual by giving or receiving unauthorized information during an examination or evaluation.

**PLAGIARISM** is an act whereby an individual represents someone else's words, ideas, phrases, sentences or data, whether oral, in print or in electronic form, including internet sources, as his/her own work. Examples include, but are not limited to:

1. Using the exact words (verbatim) of another source without quotations and appropriate referencing;
2. Using the ideas, thoughts, opinions, data or theories of another without a reference, even if completely paraphrased;
3. Using charts and diagrams from another source without revision, permission from the author and/or appropriate referencing;
4. Using facts and data from another source without a reference unless the information is considered common knowledge.
5. Copying so many words or ideas from a source that it makes up the majority of your work, whether it is cited or not

**Note:** *Online Discussions are intended to be a forum for the student to provide their unique perspective and may use a quote to convey an important piece of information by*

*the original author, however the student must accompany this quote with their context for each quote. Quotes should be used judiciously in discussions and not in place of the students thinking.*

**FABRICATION** is the deliberate use of false information or withholding of information with the intent to deceive. Examples include, but are not limited to:

1. Using information from a source other than the one referenced;
2. Listing of references in a bibliography that were not used in a paper;
3. Falsifying or withholding data in experiments, research projects, notes, reports, or other academic exercises;
4. Falsifying or withholding data in patient charts, notes or records;
5. Submitting papers, reports or projects prepared in whole or part by another;
6. Taking an exam for another or allowing another to take an exam for oneself.

**OTHER ACTS OF MISCONDUCT** include, but are not limited to:

1. Changing, altering or falsifying a graded examination, completed evaluation, grade report form or transcript, or unauthorized entry, or assisting another in unauthorized entry, into a University building, office or confidential computer file for that purpose;
2. Obtaining, distributing, accepting or reviewing examinations, lab reports or other confidential academic materials without prior and explicit consent of the instructor;
3. Submitting written or computer work (in whole or in part) to fulfill requirements of more than one course without the prior and explicit permission of both instructors;
4. Impeding the progress of another by sabotaging their work (written or computer data, laboratory experiments, etc.), deliberately providing false or misleading information, or withholding or hiding information, books or journals;
5. Stealing information from another;
6. Forging an instructor's signature or initials on examinations, evaluations, lab reports or other academic materials, and forgery, alteration, or misuse of School documents, records or identification.
7. Obstruction or disruption of teaching, research, administration, procedures, or other School activities;
8. Theft, damage, or the threat of damage to the property of the state or a member of the University community or to any person lawfully on the university campuses;
9. Any action that harms, threatens bodily harm or presents an imminent danger of such to any person lawfully on the university campuses;
10. Possession or use of firearms, explosives, dangerous weapons on university property in violation of federal, state or local law or university regulations.

11. Use, possession, or distribution of narcotics or dangerous drugs, the use of which is prohibited by laws of the state;
12. Unauthorized entry into, or use of, University facilities;
13. Violations of established University policies or regulations, including regulations concerning consumption of alcoholic beverages or other substances, and any other procedure or regulation officially promulgated by the University.
14. Violations of any applicable professional Codes of Ethics.

Portions of this Honor Code have been adapted with permission from the administration of Ramapo College.