DREXEL UNIVERSITY
College of
Medicine
Department of Pharmacology and Physiology

DRUG DISCOVERY AND DEVELOPMENT GRADUATE PROGRAM

Policies & Procedures

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POLICIES AND PROCEDURES FOR

MASTER OF SCIENCE PROGRAM IN DRUG DISCOVERY AND DEVELOPMENT

I. MISSION STATEMENT

A. Statement of the Goals of the Program

The overall goal of this Program is to provide students with an intensive, multifaceted classroom experience along with diverse research opportunities to prepare graduates for a career in the field of Drug Discovery and Development. The Program covers all aspects involved in the discovery, development and commercialization of drugs. Depending on a student's preferences, there are multiple options and areas of concentration that can be pursued using elective courses in different departments, schools and colleges. The biomedical sciences are the foundation of this field so the initial emphasis of the program is on the disciplines of Pharmacology and Physiology. The pharmaceutical and biotechnology industries are complex, highly specialized, constantly evolving, and require a diversity of expertise. There are numerous technical specialties required and diverse organizational disciplines necessary to successfully advance a candidate compound to an approved drug. Consequently the program has been designed to provide a solid foundation in the sciences as well as an in depth exposure to the entire process of drug discovery and development. This is coupled with opportunities to do hands-on laboratory research or industry internships and further focus training on individual segments or disciplines within the field. In addition to several experienced faculty, we have successfully attracted individuals from all levels and sectors of the pharmaceutical industry to participate in the development and delivery of the Program. The Program also capitalizes on the rich and diverse resources available within the Drexel University academic community to draw on courses available in the LeBow College of Business, the Dornsife School of Public Health, the Close School of Entrepreneurship and other departments and schools at the University.

B. Statement of the Career-oriented Outcomes of the Program

By providing in depth exposure to the multiple elements associated with drug discovery and development, this program provides graduates with numerous rewarding career options. For recent undergraduates, it provides entrance into a competitive field with multiple opportunities for growth and advancement. For active professionals, it provides valuable training to advance in their discipline or make a smooth and successful transition to another discipline within the field. For students who continue their training in advanced or professional degree programs, it provides an added expertise that will help set them apart from their colleagues. Graduates of the program are prepared to assume positions in pharmaceutical and biotechnology companies, nonprofit foundations, government agencies and academic institutions.

II. PLAN OF STUDY (SEE ATTACHED TEMPLATE)

A. Required Courses

All students in the Drug Discovery and Development Program are required to take the following programmatic courses: Drug Discovery and Development I and II, which provide a comprehensive overview of the discovery and development process; Graduate Pharmacology and Advanced Topics in Pharmacology which provide a solid foundation in this key interdisciplinary science; Drug Discovery and Development Research, which is intended to provide hands on or practical experience; and Current Topics in Pharmacology which is a seminar/discussion course that provides valuable opportunities to enhance presentation skills. All students in the Graduate School are required to take Scientific Integrity and Ethics and Biostatistics or Statistics for Neuro/Pharm Research.

Required Courses		**Credits Hours**
IDPT 500S	Responsible Conduct of Research[1]	2.0
NEUR 500S	Statistics for Neuro/Pharm Research[2]	2.0
PHRM 512S	Graduate Pharmacology*	3.0
PHRM 525S	Drug Discovery and Development I*	3.0
PHRM 526S	Drug Discovery and Development II	3.0
PHRM 605S	Research in Drug Discovery and Development	4.0
PHRM 502S	Current Topics in Pharmacology & Physiology	1.0
PHRM 517S	Advanced Topics in Pharmacology	1.0
	Total	**19.0**

[1]CR 612S* may be substituted for IDPT 500S
[2]CR 520* may be substituted for NEUR 500S

* *course available online*

All students must register and participate in the seminar/discussion course (Journal Club) Current Topics in Pharmacology and Physiology every semester while in the program up until registering for Thesis Defense. It is expected that each student will complete at least one research rotation in Drug Discovery and Development Research. The Program Director(s) will advise each student on the selection of the flexible aspects of the curriculum such as choice of electives.

B. Elective Courses

In consultation with the student's advisor and according to the anticipated area of interest, the student is required to select elective courses totaling a minimum of 19 credits from a diverse range of topics that complement the core curriculum and which provide relevant, in-depth knowledge to enhance career options. Onsite students who are interested in discovery research are encouraged to take Graduate Physiology and Advanced Topics in Physiology. They are also encouraged to repeat Current Topics in Pharmacology and Physiology if their schedule permits. Courses outside of the Drug Discovery and Development program may be taken on the advice and with the permission of the Program Director and the faculty mentor.

A list of potential electives is provided below. It is recommended that you consult with the course director for each course to receive approval to register for the course and to determine if there are prerequisites or class limitations. For courses outside the College of Medicine, please consult the Graduate catalog at http://catalog.drexel.edu/coursedescriptions/quarter/grad/

Approved Electives

MIIM 521S	Biotechniques I*	2.0.
MIIM 524S	Vaccines and Vaccine Development*	3.0
MIIM 530S	Fundamentals of Molecular Medicine I*	3.0
MIIM 531S	Fundamentals of Molecular Medicine II*	2.0
MLAS 536S	Animal Models for Biomedical Research	1.0
NEUR 507S	Graduate Neuroscience I	3.0
MIIM 508S	Immunology I*	3.0
BIOC 510S	Cancer Biology	3.0
PHGY 503S	Graduate Physiology	4.0
PHRM 503S	Pharmacology & Physiology Lab Rotation	4.0
PHRM 507S	Principles of Neuropharmacology	3.0
PHRM 516S	Advanced Topics in Physiology	1.0
PHRM 518S	New Frontiers in Therapy	1.0
PHRM 519S	Methods in Biomedical Research	2.0
PHRM 520S	Internship in Drug Discovery	4.0
PHRM 521S	Intensive Internship in Drug Discovery and Development	9.0
PHRM 999S	Special Topics in Pharmacology and Physiology	2.0
CR 500S	Epidemiology*	3.0
CR 505S	Ethical Issues in Research*	3.0
CR 513S	Pharmaceutical R&D: Business Process and Information Flow*	3.0
CR 514S	Worldwide Regulatory Submissions*	3.0
CR 515S	Introduction to Clinical Trials*	3.0
CR 520S	Applications of Clinical Research Biostatistics*	3.0
CR 525S	Scientific Writing and Medical Literature*	3.0
CR 530S	Tech Transfer*	3.0
CR 535S	Current Regulatory Issues in Biomedical Research*	3.0
CR 545S	Pharmaceutical Law*	3.0
CR 550S	Leadership Skills*	3.0
CR 555S	Compliance and Monitoring Issues*	3.0
CR 560S	Special Topics*	3.0
CR 570S	Principles and Practice of Pharmacovigilance*	3.0
CR 600S	Designing the Clinical Trial*	3.0
CR 609S	Innovative Produce Development*	3.0
CR 612S	Fundamentals of Compliance*	3.0
CR 614S	Pharmacotherapy in New Drug R&D*	3.0
CR 616S	Intro to Therapeutic Products*	3.0
CR 617S	Informatics in Pharmaceutical Research & Development*	3.0

CR 620S	Biotech/Research*	3.0
CR 625S	Health Policy and Economics*	3.0
CR 635S	Strategic Planning*	3.0

** course available online*

Approved Electives (quarter-based)

BIO 631	Bioinformatics I	3.0
MGMT 685	Implementing Strategies Using Project Teams	3.0
MGMT 910	Readings in Strategic Management	3.0
PROJ 501	Introduction to Project Management	3.0
PROJ 535	International Project Management	3.0
PBHL 530	Principles of Epidemiology	4.0
BMES 604	Pharmacogenomics	3.0
MGMT 940	Seminar in Organizational Behavior	3.0
ORGB 625	Leadership and Professional Development	3.0

Note: *One quarter credit is equal to two-thirds of a semester credit for satisfying program credit requirements*

C. Suggested Curriculum

Full-Time Plan of Study

Fall Semester I	**Credit Hours**
• Graduate Physiology	4.0
• Advanced Topics in Physiology	1.0
• Drug Discovery & Development I	3.0
• Responsible Conduct of Research	2.0
• Current Topics in Pharmacology and Physiology	1.0

Spring Semester I	
• Drug Discovery and Development II	3.0
• Research in Drug Discovery & Development	4.0
• Biostatistics or Statistics for Neuro/Pharm Research	2.0
• Current Topics in Pharmacology and Physiology	1.0
• Elective(s)	3.0

Fall Semester II	
• Graduate Pharmacology	3.0
• Advanced Topics in Pharmacology	1.0
• Current Topics in Pharmacology and Physiology	1.0
• Special Topics in Drug Discovery & Development	2.0
• Elective(s)	3.0

Spring Semester II

- Thesis Research OR 9.0
- Intensive Internship OR 9.0
- Elective(s) 9.0

Online/Part-Time Plan of Study

Semester 1	**Credit Hours**
Drug Discovery & Development I	3.0
Elective 1	1.0
Semester 2	
Drug Discovery and Development II	3.0
Applications of Clinical and Research Biostatistics	3.0
Current Topics in Pharmacology and Physiology	1.0
Semester 3	
Graduate Pharmacology	3.0
Advanced Topics in Pharmacology	1.0
Fundamentals of Compliance	3.0
Semester 4	
Elective 2	3.0
Elective 3	3.0
Semester 5	
Research in Drug Discovery & Development	4.0
Elective 4	2.0
Semester 6	
Elective 5	3.0
Elective 6	3.0

The Office of Biomedical Education has established criteria by which all students in all graduate programs will be uniformly evaluated. A grade of B must be earned in each required course. Programmatic courses must be repeated if the student earns a grade below a B in that particular course. Programmatic courses in which a student has earned a grade of B- can be remediated to a B. Students must maintain a grade point average of at least 3.0. If their average falls below 3.0, they will automatically be placed on academic probation.

D. Research Internships

An internship is a highly desirable component of the training program in Drug Discovery and Development and provides a unique opportunity for the student to apply the didactic knowledge

gained in the laboratory in a professional setting. The internship experience can be utilized to obtain specialized training in a branch of the field that the student intends to pursue after graduation or it can provide valuable diversification to a student's background. Internships may be arranged with pharmaceutical companies, biotech companies, contract research organizations, foundations, government agencies or academic institutions. Several of these organizations have established formal internship or co-op programs that would be appropriate for this experience. Students are expected to arrange an internship with the assistance of the Program faculty to take place after the Spring semester of their 1st year.

E. Journal Clubs and Seminars

Performance Criteria for Current Topics in Pharmacology & Physiology (face-to-face):
Three unexcused absences are allowed per year for journal clubs. More than three absences will result in a grade of Unsatisfactory (U). The "U" must be remediated to the satisfaction of the course director.

III. ADDITIONAL REQUIREMENTS FOR GRADUATION (PROGRAM SPECIFIC)

A. GPA Requirements – Required Courses

The Office of Biomedical Education has established criteria by which all students in all graduate programs will be uniformly evaluated. A grade of B must be earned in each required course. Programmatic courses must be repeated if the student earns a grade below a B in that particular course. Programmatic courses in which a student has earned a grade of B- can be remediated to a B.

B. Overall GPA Requirements – Program

Students must maintain a grade point average of at least 3.0. If their average falls below 3.0, they will automatically be placed on academic probation.

C. Laboratory Rotation

Laboratory rotations must be arranged in consultation with the Program Director and faculty of the Program. The research areas may be chosen to complement the student's long-term research interests. Research rotations should provide an opportunity to:

- Practice scientific logic and experimental design
- Acquire useful technical expertise
- Extend scientific and personal interactions within and between labs
- Explore the possibility for a future Thesis research topic
- Develop presentation skills

At least 20 hours per week (minimum) for a three-month period are required for each rotation. An oral presentation of the research experience is prepared by the student at the end of each rotation, presented to the department and evaluated by the faculty and the students. Students must complete a rotation evaluation form with their mentor upon completion of their rotation which must be filed with the Program Director and the Biomedical Graduate Studies office.

Performance Criteria for Laboratory Rotations
Laboratory rotations are graded on a Satisfactory (S) or Unsatisfactory (U) basis. Students receiving an "S" are rated on a performance scale ranging from Outstanding (1) to Poor (5). A

"U" for a lab rotation is reserved for students that do not meet performance requirements, including attendance, of the rotation as stipulated by the program.

IV. NON-THESIS TRACK

A. Course Requirements

The Drug Discovery and Development Program offers a non-thesis MS degree in which students can earn the degree by taking graduate classes and writing a literature review paper as opposed to conducting original research. The requirements for a M.S. degree without thesis are essentially the same as those described above except that preparation of a scholarly review is required in lieu of a research-based thesis. The student is encouraged to choose a faculty or external mentor no later than the end of the Fall semester of the second year. External mentors must be approved by the Program Director who will help to insure that the student is making adequate progress. The role of the mentor is to provide guidance in selecting the topic for the scholarly review, and in helping the student perform the literature search, and, in writing the document. The selected topic must be approved by the Scholarly Review Committee.

B. Scholarly Review

The scholarly review covers a topic in detail based on primary research literature. The body of the paper must be 35-50 double spaced pages (12 pt font). This page number does not include citations but citations must be provided as well. The following format must be followed:

- Abstract (250 words)
- Body of Paper
  - Introduction – what is the purpose and scope of the review
  - Literature review – review and contrast findings in the field; identify unresolved issues and shortcomings of technical approaches
  - Summary – what are the key findings of the review
  - Conclusion- what gaps in our knowledge or unanswered questions emerge from the review; what are potential future directions for research in this area.

Successful completion of the literature review will be subject to the approval of the mentor/advisor and the Scholarly Review Committee. The student is strongly encouraged to produce a document of sufficient quality to merit consideration for publication.

C. Scholarly Review Committee

By the end of the third semester, the student will propose 3 members of the faculty to serve on the Advisory Committee subject to approval by the Program Director. Once formed, this committee will meet approximately every three months to review the student's progress. The committee consists of at least three voting members who must be Graduate School faculty. The student's mentor/advisor is a voting member of the Committee but cannot chair the Committee. It is also the responsibility of the Chair to ensure that there is sufficient balance on the committee to ensure a rigorous and unbiased critique of the student's project and progress. Following the quarterly review by the Committee, a brief statement of the student's progress must be signed by each Committee member and submitted to the Program Director.

D. Review Proposal

1. Students will present their Review Proposal to their Review Committee. The Proposal document will be submitted by the student after completion of the Fall semester courses of the 2nd year of study. Under special circumstances this can be extended (no more than 6 months but all proposals for extensions will be given due consideration). The Review Proposal must include an abstract and planned table of contents and be handed in one week prior to the formal presentation of the Proposal to his/her Review Committee unless otherwise specified by the Chair of the Committee. Upon approval of the Proposal, the student will continue with his/her literature research, culminating with the submission of the Review.

2. At the time of the proposal the student will present a brief (10-15 minute) oral summary of his/her intended Review followed by a detailed question and answer session with the Review Committee.

3. The Review Committee will then reach a decision. If the decision is positive, the student may continue with his/her literature research. If the decision is negative, the student can re-submit a revised or new proposal in one month.

E. Review Evaluation

1. Typewritten or photocopies of the scholarly review must be distributed to each member of the advisory committee for evaluation. The review can be submitted no less than 8 calendar weeks after satisfactory completion of the Proposal, and with the approval of his/her advisor.

2. The Review Committee will review the document within two weeks of submission.

3. The Review Committee shall decide upon the merits of the Scholarly Review. To be recommended for a Master's degree, the candidate must receive unanimous approval of the Committee. By permission of the Committee a candidate who has failed the final evaluation may present a revised document for re-evaluation after one, but not more than six months.

V. THESIS TRACK

A. Thesis Requirements

The thesis project need not be independent but rather must be at the suggestion and guidance of the major advisor. The project must be appropriate for completion and thesis defense no later than August of the second year. Laboratory work can begin during the summer after the first year and continue through the second year.

B. Thesis Committee

By the end of the third semester, the student will propose members of the faculty to serve on the Thesis Committee subject to approval by the Program Director. Once formed, this committee will meet every three months to review the student's progress. The committee consists of at least three voting members who must be Graduate School faculty from the Drug Discovery and Development or Pharmacology & Physiology Graduate Programs. The student's major advisor is a voting member of the Committee but cannot chair the Committee. The Chair of the Committee must not be a collaborator on the student's research project and

must not have any apparent conflicts of interest related to the publication or funding of the student's project. It is also the responsibility of the Chair to ensure that there is sufficient balance on the committee to ensure a rigorous and unbiased critique of the student's project and progress. Following the quarterly review by the Committee, a brief statement of the student's progress must be signed by each Committee member and submitted to the Program Director.

C. Thesis Proposal

1. Master's degree students will present their thesis proposal to their Thesis Committee. The Thesis Proposal document will be submitted by the student after completion of the Fall semester courses of the 2nd year of study. Under special circumstances this can be extended (no more than 6 months but all proposals for extensions will be given due consideration; approval must be obtained through written request to the Program Director). The Thesis Proposal must include an abstract and planned table of contents and be handed in one week prior to the formal presentation of the Thesis Proposal to his/her Thesis Committee unless otherwise specified by the Chair of the Committee. Upon approval of the Thesis Proposal the student will continue with his/her thesis research, culminating with the presentation of the M.S. thesis for defense.

2. At the time of the proposal the student will present a brief (10-15 minute) oral summary of his/her intended research project followed by a detailed question and answer session with the Thesis Committee.

3. The Thesis Committee will then reach a decision. If the decision is positive, the student may continue with his/her thesis research. If the decision is negative, the student can re-submit a revised or new proposal in one month. If the Thesis Proposal is rejected a second time, the student will be recommended for a non-thesis Master's degree.

D. Thesis Defense

1. A written thesis is required with an oral defense before the Thesis Committee. A candidate may not present him/herself for the final thesis defense until he or she has the approval of his/her major advisor.

2. At least four weeks prior to the date of the thesis defense, the Chair of the Committee, or the Program Coordinator must notify the Office of Biomedical Graduate Studies, the Registrar's Office and all departments involved in graduate education of the scheduled date of the thesis defense. At least two weeks prior to the date of the defense, typewritten or photocopies of the thesis must be distributed to each member of the advisory-examination committee.

3. The thesis defense will take place no less than two weeks and no more than four weeks after the thesis has been distributed to the members of the examination committee, except under written direction of the Steering Committee.

4. The thesis defense will be public. The candidate will be formally introduced by his/her advisor or the Chair of the Committee. The candidate will present a 30-45 minute seminar on his/her research, followed by questions from the general audience. After this initial question and answer period, the chair will dismiss the audience. The Thesis Committee will meet in private with the candidate to complete the examination process.

5. The Thesis Committee shall decide upon the merits of the candidate's performance on the thesis defense. To be recommended for a Master's degree, the candidate must receive unanimous approval of the Committee. By permission of the Committee, a candidate who has failed the final thesis defense may present him or herself for re-examination after one, but not

more than six months. This re-examination must be taken within a calendar year of failure to pass the first examination. A report on each final thesis defense whether passed, failed, or recommended for re-examination must be filed by the Committee in the Office of Biomedical Graduate Studies.

6. Three copies of the completed thesis suitable for binding and bearing the approval of the advisory-examination Committee must be deposited in the Office of Biomedical Graduate Studies. One of these copies is to be placed on file in the COM Library, Graduate Office and the Pharmacology & Physiology Main Office. An unbound copy of the thesis must also be presented to the Office of Biomedical Graduate Studies for microfilming by University Microfilms, Ann Arbor Michigan. The abstract will be published in Dissertation Abstract by University Microfilms. The cost of preparation, reproduction and binding of additional copies for personal use are the candidate's responsibility.

VI. UNSATISFACTORY PERFORMANCE

A. Definition of Unsatisfactory Performance

Unsatisfactory performance is defined as not obtaining a final grade of "B" or better in all courses required for the completion of the Master of Science in Drug Discovery and Development degree. Unsatisfactory performance is also defined as not maintaining an overall cumulative GPA of 3.0 or better for all courses.

B. Remediation Policy

Each course will have individual remediation policies in the case of unsatisfactory performance. Please consult the syllabi for each of the courses. Remediation may range from a requirement to repeat the course, undertake a special examination, or submit a defined written assignment in addition to all other forms of assessment.

VII. ACADEMIC INTEGRITY

A. Code of Behavior

CODE OF BEHAVIOR

The Graduate Program in Pharmacology & Physiology subscribes to the **Code of Professionalism (http://www.drexelmed.edu/Portals/0/BiomedicalGraduateStudies /StudentHandbook2010.pdf)** for all of its members. This policy states that professional behavior appropriate to faculty and students in an academic research setting is expected and required at all times. Admission to and continued participation in the Graduate Program is therefore contingent upon the student's understanding of this policy, and his/her agreement to adhere to its guidelines.

B. Code of Ethics

CODE OF ETHICS

The Graduate Program in Pharmacology & Physiology subscribes to the **Code of Academic Integrity** (presented in its complete form in the Student Handbook, (**http://www.drexelmed.edu/Portals/0/BiomedicalGraduateStudies/StudentHandbook2010.pdf**) for all its members. This policy states that cheating, plagiarism, forgery, or other forms of academic misconduct are not tolerated at our institution. Admission to and continued participation in the Graduate Program is therefore contingent upon the student's understanding of this policy, and his/her agreement to adhere to its guidelines.