

College of Pharmacy

Ph.D. in Pharmaceutical Sciences Drug Discovery & Biomedical Sciences

GRADUATE STUDENT HANDBOOK

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Preface

Welcome to the University of South Carolina College of Pharmacy! The graduate faculty sincerely hope that the pursuit of your advanced degree will be productive, rewarding, and enjoyable. The policies and procedures outlined in this handbook are intended to provide a concise compilation of departmental requirements, which complement and reflect the University of South Carolina (USC) Graduate School regulations outlined in the USC Graduate Studies Bulletin. All graduate students are encouraged to understand the appropriate degree requirements described in the Academic Bulletin (<u>https://academicbulletins.sc.edu/graduate/pharmacy/pharmaceutical-sciences-phd/</u>) as well as read and become familiar with the policies and procedures outlined below. The graduate program in Pharmaceutical Sciences, Drug Discovery and Biomedical Sciences (DDBS) concentration, is administered by the Graduate Program Director and aided by Ms. Rachel McKeown. Questions concerning admission, policies, or procedures should be addressed to the Graduate Program Director. Questions relating to financial aid should be addressed to Ms. McKeown at (803) 777-0757 or <u>rachelm@cop.sc.edu</u>.

Graduate Program Philosophy

The M.S. and Ph.D. degree programs are structured to accommodate diverse research interests. In consultation with an advisor and advisory committee, the student will develop a program of study that reflects the research area. Candidates for the M.S. or Ph.D. degree are expected to conduct original research and contribute to the literature in their specific area of expertise. Therefore, all M.S. and Ph.D. candidates must submit a thesis or dissertation as appropriate, which should be evidenced or supported by publications and any relevant patent submissions. In general, each M.S. graduate student is encouraged to publish at least one paper. Each Ph.D. student is expected to publish research papers during their tenure in the degree program. Presentations at professional scientific meetings are also highly encouraged.

The primary goal of the graduate program, DDBS concentration, is to provide state-of-the-art, researchintensive education for students seeking to obtain an M.S. or Ph.D. degree. The program provides training for students to gain the research and teaching skills necessary to become successful independent scientists. Graduates are expected to be pharmaceutical scientists. Therefore, students are exposed to interdisciplinary training and education while seeking an advanced degree in pharmaceutical sciences. Topics stressed in this process include pharmacogenetics and genomics; synthesis and design of new medicinal agents; examination of biochemical, pharmacological and toxicological actions; bioavailability, excretion and dosage formulation considerations. Exposure of students to interdisciplinary training begins in the first year of enrollment courses covering topics in medicinal chemistry, pharmaceutics. with common core pharmacogenomics, and pharmacology. Upon completing the courses, the student, in consultation with the major advisor and advisory committee, takes additional courses that will contribute to their training and research specialization. Further interdisciplinary training is obtained by completing required didactic courses with team-taught recitation sections and participating in the departmental seminar programs.

Successful candidates with an advanced degree in Pharmaceutical Sciences will be prepared for diverse professional career choices. These include teaching and research at academic institutions, research and development in the pharmaceutical, biotechnology and diagnostics industries, contract research organizations, pharmaceutical sales, regulatory governmental agencies (e.g., The Food and Drug Administration), diagnostic and toxicology laboratories, drug discovery and development consultation, and drug and law enforcement (forensic science).

General University Academic Requirements and Procedures

Admission Regulations

The graduate admissions committee in the Department of Drug Discovery and Biomedical Sciences reviews all applications to the M.S. and Ph.D. programs. The following are the basic requirements:

- 1. A bachelor's degree or its equivalent from an accredited college or university, comparable in standard to that awarded by USC.
- 2. Satisfactory scores on the Graduate Record Examinations (GRE)
- 3. Intellectual promise, including evaluation of grade point averages (GPA) that indicates an ability to do acceptable graduate work
- 4. Strong personal qualifications, including good moral character

Credentials for admission must include a complete record of all previous college or university work. including undergraduate research experiences. Admission to the M.S. or Ph.D. degree program is available to students with a biology, chemistry, or pharmacy degree (or related area) from an accredited college or university. Students should have satisfactorily completed the following undergraduate courses: one year each of general and organic chemistry, one year of physics, and calculus. Information policies, and the admission process obtained regarding programs, can be at also The College frequently https://www.sc.edu/study/colleges_schools/graduate_school/index.php. awards instructional, clinical, and research assistantships to graduate students in Drug Discovery and **Biomedical Sciences.**

All students must be officially admitted by the Dean of the USC Graduate School, following the recommendation of the admissions committee of the appropriate graduate program. Admission is for the specific purpose stated by the USC Graduate School, and the student must reapply to pursue further study or change the degree sought. Non-degree students must also be admitted to the USC Graduate School. Note that students are allowed to obtain a degree in accordance with the regulations in place at the time they are admitted to degree candidacy. A student may also utilize regulations established after admission to degree candidacy. However, all regulations chosen must be outlined in only one specific graduate bulletin.

For full consideration, applications for the upcoming academic year should be completed before January 31. However, candidates may apply for admission at any time. Notification of acceptance will usually be made before April 15 for matriculation the following fall semester.

INTERNATIONAL STUDENTS

In accordance with the graduate bulletin, students whose native language is not English must take a diagnostic test to assess their capabilities in English shortly after arrival on campus. English speaking capability will be assessed in a mandatory workshop held by the USC Graduate School in August or January of each academic year. Those students who are deficient in writing, reading, or speaking English will be provided opportunities for further study.

NEW STUDENT ORIENTATION

Upon arrival, each student should meet with the Graduate Program Director for

- Initial orientation and overview of information found in the Graduate Student Handbook.
- Course advisement for registration. When needed, the Graduate Program Director will serve as temporary advisor for class registration during the first semester. The student's research advisor will be responsible for course advising in subsequent semesters.
- Introduction to the Individual development plan (IDP) for research and career guidance. If needed, IDP instructions and a template are available at the office of the Vice President for Research website:

https://www.sc.edu/about/offices and divisions/research/support for researchers/index.php

- Assignment of teaching or clinical assistantship duties, if applicable.
- Discussion of the expected amount of time to spend in the research laboratory, absences, vacation, and USC holidays, as applicable.
- Assignment of building keys.

Upon arrival, each student should meet with Ms. McKeown for

- The university-required background check.
- Student health insurance information, including information regarding counseling available through the Student Health Center.
- Completing all hiring forms, including the I-20 and I-94 forms (these will require identification such as a driver's license, passport, and a social security card).

Course Regulations

COURSE LOADS

A student with a course load of nine or more credit hours during the fall and spring semesters is classified as full-time.

A student hired to fill a teaching, clinical, or research assistantship with a course load of six or more credit hours during the fall and spring semesters is classified as full-time.

All students are required to enroll for at least one credit hour during any semester in which thesis or dissertation progress is made or when resources of the University are utilized.

AUDITING A COURSE

A student must attend at least 75 percent of all classes in a course to receive audit credit. Under no circumstances will a student be allowed to repeat an audited course for credit.

DROPPING A COURSE

Per USC policy, W is assigned for student withdrawal from a course after the late registration period but before the drop date. A WF, which counts as an F in GPA calculation, is assigned for student withdrawal from a course after the drop date prescribed in the USC Academic Calendar. Students who must withdraw from all courses due to compelling circumstances may petition the Graduate Program Director to receive grades of W rather than WF in those cases where a WF is assigned.

GRADING SYSTEM

The grading system utilized by the University of South Carolina is based on a 4-point system. The letter grades A, B, C, D, and F are used to designate excellent, good, fair, poor, and failing. A grade of D+ or lower cannot be applied to degree programs.

I=Incomplete – Is assigned when a student is prevented from completing some portion of work in a course. The instructor must submit a grade change form to the Office of the Registrar explaining the reasons for the incomplete and provision made to complete the course. The grade of 'I' is not utilized in computing a student's grade point average but will be permanently changed to an "F" after a 12-month period.

NR=No record – The grade is not appropriate for the course or has not been submitted. The grade of NR must be appropriately replaced before the last week of the fall or spring semester immediately following the semester that the 'NR' was recorded, or an "F" will be assigned.

W=Withdrawn Without Penalty

WF=Withdrawn with Penalty, which counts as an F in the GPA calculation

S or U=Satisfactory or unsatisfactory, respectively, and may only be utilized in accordance with approved "pass-fail grading." Courses completed with a grade of "S" may count as credits earned.

T or U=Satisfactory or unsatisfactory progress, respectively, toward completion of a thesis or dissertation. These grades are utilized for thesis or dissertation preparation courses designated as PHAR 799 (M.S.) or PHAR 899 (Ph.D.). Although they count as credits earned, these grades are not utilized in computing the student's grade point average.

The following grading scale will be utilized for DDBS PHAR graduate courses:

A 90–100.00 B+ 85–89.99 B 80–84.99 C+ 75–79.99 C 70–74.99 D+ 65–69.99 D 60–64.99 F < 59.99

Academic Standards

- Graduate courses taken for degree credit must be passed with a "C" or better.
- The student must maintain a grade point average of at least 3.0. Graduate degree-seeking students whose cumulative grade point average drops below 3.00 (B) will be placed on academic probation and allowed one calendar year in which to raise the grade point average to at least 3.00. Students who do not reach a cumulative 3.00 grade point average during the probationary period will not be permitted to enroll for further graduate course work as a degree or non-degree student. Please see the full details of academic regulations at the USC Graduate School webpage: https://academicbulletins.sc.edu/graduate/policies-regulations/graduate-academic-regulations/.
- A student accumulating 12 credit hours with a grade of "C+" or below in graduate courses taken at the University will not be eligible for a graduate degree. This regulation will remain in effect for 6 years for the M.S. degree program and 8 years for the Ph.D. degree program.

Grade Changes, Appeals and Petitions

A grade in a course may be changed only by the professor of record in the course, and then only within one year following the initial grade assignment. All appeals and petitions regarding other academic or curriculum matters must utilize the following procedures.

- The nature of the appeal and justification must be submitted in writing to the student's research advisor and graduate committee chairman.
- The graduate committee chairman will notify the Graduate Program Director and call a meeting of the student's graduate committee.
- The student's graduate committee will issue an advisory opinion on the petition or appeal and submit it in writing to the Graduate Program Director, who will render a decision.
- In the event of an unfavorable decision, the student may request that the graduate program director call a meeting of the graduate faculty which will rule on the appeal or petition and forward it in writing to the Graduate Program Director. In the case of further denial, additional appeals may be made to the USC Graduate School in accordance with the Graduate Bulletin.
- For consultation regarding any concerns or conflicts, students may confidentially discuss the situation with the Graduate Program Director or contact the USC Graduate School Ombudsman (<u>https://www.sc.edu/study/colleges_schools/graduate_school/opportunities_support/ombuds/index.php</u>). The Ombudsman provides confidential and independent resources for graduate students to help ensure a fair and equable administration of the Graduate Program.

Dismissal from the Graduate Program

A graduate student in either the M.S. or the Ph.D. programs will be subject to dismissal from the USC Graduate School and the Graduate Program in the College of Pharmacy for any of the following reasons:

- A cumulative G.P.A. below 3.0 beyond the probationary period of one year described above.
- Accumulation of 12 hours of 'C' in courses taken at USC.
- Lack of satisfactory and continued progress towards completion of the degree.
- Conviction of sexual harassment in the workplace.
- A preponderance of evidence, confirmed by the thesis or dissertation committee, for research misconduct such as deliberate fabrication and falsification of research results or evidence of plagiarism.

Degree Requirements and Curricula

General Requirements

The typical length of time required to complete the M.S. degree is 2 years and is 5 to 6 years for the Ph.D. degree. Further degree-specific requirements are found in the Ph.D. and M.S. degree requirements below. A student with prior graduate course work may transfer up to nine credit hours for graduate credit.

All students (M.S. and Ph.D.), in consultation with their major advisor and advisory committee, must develop an individualized program of study. An average grade of "B" or better is required in all courses within a student's program of study and grades below "C" are considered as failure. *Students must also participate in the departmental seminar program (PHAR 712) every semester during the student's tenure in either degree program.* It is highly recommended that eligible graduate students apply for an NIH F31 grant. Guidance and a template can be provided by the student's advisor and the Graduate Program Director.

Doctor of Philosophy Degree

All students must successfully complete at least 60 hours of graduate course work. In addition to the general requirements listed above, candidates for the Ph.D. degree are required to complete four departmental seminar courses (PHAR 712A-D). A maximum of 4 hours credit can be earned for PHAR 712. All students are required to submit a dissertation based upon original research, meeting all requirements of the USC Graduate School, and expected to submit at least one manuscript for publication prior to award of the degree. Further degree requirements are listed below.

Ph.D.-Pharmaceutical Sciences (60 Hours) Required Courses:

- PHAR 700 Principles of Pharmacology, Medicinal Chemistry, and Pharmaceutics 4 hours
- PHAR 701 Current Topics in Pharmaceutical Sciences 4 hours
- PHAR 712A Seminar in Pharmaceutical Sciences 1 hour¹
- PHAR 712B Seminar in Pharmaceutical Sciences 1 hour¹
- PHAR 712C Seminar in Pharmaceutical Sciences 1 hour¹
- PHAR 712D Seminar in Pharmaceutical Sciences 1 hour¹
- ELECTIVE 12 hours of electives²
- PHAR 896 Doctoral Directed Research 24 hours³
- PHAR 899 Dissertation Preparation 12 hours

¹ A maximum of 4 hours credit can be earned for PHAR 712.

² Electives will be chosen based on the needs of the graduate student. Areas of emphasis include Biomedicinal Chemistry, Synthetic Medicinal Chemistry, Pharmaceutics, and Pharmacology. Electives will be chosen based on the area of emphasis and must be approved by the Ph.D. advisory committee and the Graduate Program Director. Electives must be 700 level and above, or any course approved by the USC Graduate School for Graduate Credit.

³Other didactic electives may be applied toward the total hours of credit required if approved by the Ph.D. advisory committee.

Pharm.D. and Ph.D. Degree

All students must successfully complete at least 60 hours of graduate course work. All students are required to submit a dissertation based upon original research, meeting all requirements of the USC Graduate School prior to award of the degree. Further degree requirements are listed below.

Courses for the concurrent Pharm.D. and Ph.D. degree (60 hours minimum)

In addition to the general requirements listed for the Ph.D., students pursuing the Pharm.D. and Ph.D. concurrently will take elective courses that are approved for graduate credit and fulfill requirements for the Ph.D. program. Up to twelve (12) credit hours from the Pharm.D. curriculum can count toward both degrees, with the following stipulations. The student must have completed at least 90 hours of undergraduate course work, have a minimum GPA of 3.40, and have form G-ABGSP (Accelerated Bachelor's/Graduate Study Plan Authorization, which was previously known as form GS-59) on file in the USC Graduate School (https://www.sc.edu/study/colleges_schools/araduate_school/documents/g_abgsp_accelerated_bachelors_graduate_study_plan_coursework_authorization.pdf). Grades of B or higher must be earned for the course to count for graduate credit. At least half of the electives must be numbered 700 or above. Courses numbered 500-699 are acceptable only if they have been approved for graduate credit. Graduate courses taught in units other than pharmacy must be approved by the graduate faculty of pharmacy as appropriate for a Ph.D. degree in pharmaceutical sciences. Registration for each course requires approval of the student's advisor, the chair of the student's department, the Graduate Program Director of the Ph.D. program, and the dean of the USC Graduate School. Form G-ABGSP must be processed for each graduate credit course at the time of registration to permit the registrar's office and the USC Graduate School to properly enroll and code the student for enrollment in a course for graduate credit.

Required Courses

- PHAR 712A Seminar in Pharmaceutical Sciences
- PHAR 712B Seminar in Pharmaceutical Sciences
- PHAR 712C Seminar in Pharmaceutical Sciences
- PHAR 712D Seminar in Pharmaceutical Sciences
- PHAR 896 Doctoral Directed Research (up to 29 Hours)²
- PHAR 899 Dissertation Preparation

Up to twelve graduate-level credit hours taken for the Pharm.D. degree¹

Two to five graduate-level courses not taken for the Pharm.D. degree, 7-15 hours

¹Courses must be approved by the Ph.D. advisory committee as appropriate for the DDBS track.

²Other didactic electives may be applied toward the total hours of credit if approved by the Ph.D. advisory committee.

Master of Science Degree

All students must successfully complete at least 30 hours of graduate course work. In addition to the general requirements listed above, candidates for the M.S. degree are required to complete two departmental seminar courses (PHAR 712A-B). A maximum of 2 hours credit can be earned for PHAR 712. All students are required to submit a thesis based upon original research, meeting all requirements of The USC Graduate School prior to award of the degree. Further degree requirements for each specialty are listed below. No more than nine hours of credit for PHAR 799 will be allowed for thesis research and writing. Further degree requirements for each specialty area are listed below.

M.S.–Pharmaceutical Sciences (30 Hours)

Required Courses

- PHAR 700 Principles of Pharmacology, Medicinal Chemistry, and Pharmaceutics 4 hours
- PHAR 701 Current Topics in Pharmaceutical Sciences 4 hours
- PHAR 712A Seminar in Pharmaceutical Sciences 1 hour¹
- PHAR 712B Seminar in Pharmaceutical Sciences 1 hour¹
- ELECTIVE 11 hours of electives²
- PHAR 799 Thesis Preparation 9 hours

Notes:

¹A maximum of 2 hours credit can be earned for PHAR 712.

²Electives will be chosen based on the needs of the graduate student. Areas of emphasis include Biomedicinal Chemistry, Synthetic Medicinal Chemistry, Pharmaceutics, and Pharmacology. Electives will be chosen based on the area of emphasis and must be approved by the advisory committee and the Graduate Program Director. Electives must be 700 level and above, or any course approved by the USC Graduate School for Graduate Credit.

Ph.D. Degree Progression

Summary of Ph.D. Degree Progression

The Doctor of Philosophy degree is considered the mark of highest achievement in preparation for creative scholarship and research. It is the highest degree conferred by universities and, by nature and tradition, is a research degree. Though formally admitted to the Graduate Program in Pharmaceutical Sciences, earning a Ph.D. entails completing all coursework, passing the qualifying and comprehensive exams, moving a research project forward in a substantive and demonstrable manner, writing and defending a dissertation, and completing the program requirements described in this Handbook. Please note that admission to the program does not guarantee a degree. The following is a brief outline of the steps required during the progression to the Ph.D. and a timeline for each step. *Forms mentioned USC below available at the Graduate School forms library website: are https://www.sc.edu/study/colleges schools/graduate school/forms library/index.php

- 1. Completion of all required course work by the end of the degree program. The core curriculum should be completed by the end of the second year.
- 2. Selection of a Research Advisor must occur no later than the beginning of the second year.
- 3. Selection of the Graduate Committee. A graduate committee must be selected by **the end of the second year**. The student must notify the Graduate Program Director in writing of the committee's composition using the G-DCA 'Doctoral Committee Appointment Request' *form.
- 4. The Ph.D. Program of Study form must be completed prior to the IRP/qualifying examination. Students must use the DPOS 'Doctoral Program of Study' *form. Following approval of the Graduate Committee, the student as well as the Research Advisor must sign the Program of Study and forward the document to the Graduate Program Director.
- 5. Submission and Defense of the Initial Research Proposal (IRP). The IRP/qualifying examination must be completed by the end of the second year. The topic of the proposal is the student's planned Ph.D. research project and is written in the style of an NIH grant application. The IRP must be distributed to all committee members at least five business days prior to the scheduled committee meeting. The student must then orally present and defend the proposal to the Ph.D. Graduate Committee. Additional details are provided below. Also note: Although not formally required, students are encouraged to schedule meetings with their graduate committee on an annual basis to provide research progress updates and seek guidance on their research.
- 6. The Comprehensive Oral/Written Examination must be taken no later than the **end of the 3rd year** in the student's degree program. In consultation with the comprehensive exam committee, the dissertation advisor will select three abstracts in an area outside of the student's immediate dissertation research focus. The three abstracts are given to the student on the morning of the examination, no later than 6 hours ahead of the oral presentation. The student will select one abstract as a basis for preliminary data to develop a presentation outlining thoughtful and hypothesis-driven follow-up experiments or projects. The meeting will convene the same afternoon, where the student will present and defend the proposed project. If a pass is issued for the oral portion of the exam, the student will summarize the proposal in writing, addressing critiques and suggestions from the discussion during the meeting. This will be in the form of an NIH-style research proposal. The student will typically have up to seven days to complete the written portion. Additional details are provided below.
- 7. Pre-defense committee meeting: It is <u>highly recommended</u> that the dissertation committee be convened for an update and discussion of target completion date of the dissertation **approximately 6 months prior to the dissertation defense date**. This meeting will provide a framework of understanding for the advisor and student regarding aspects of the project that need to be completed to graduate from the program. This meeting is called by the graduate student in consultation with the dissertation advisor.
- 8. Dissertation completion.
- 9. Dissertation Seminar/Defense.

Introduction

A Ph.D. progress sheet has been developed to facilitate monitoring the progress and status of each graduate student in the Program. The deadlines and requirements listed on the sheet are mandated by both the College of Pharmacy and the Graduate School of the University of South Carolina and must be completed before the Ph.D. degree will be awarded by the USC Graduate School. If these requirements are not met in a timely fashion, progress towards completing the Ph.D. degree will be jeopardized. Summer school sessions are not counted in calculating the deadlines. Each student is expected to track their status of meeting each deadline. If the student does not meet the deadlines in a reasonable manner, the Graduate Program Director will notify the student in writing, requesting details concerning how and when the deadline(s) will be satisfied. The Ph.D. program must be completed within 8 years after enrollment in the degree program. Any course taken that is more than 8 years old cannot be used towards the completion of the degree.

Admission to Ph.D. Candidacy

All students must be Admitted to Candidacy to pursue the Ph.D. degree. Admission to candidacy is a two-part process.

Part I

Part I of the Admission to Candidacy is satisfied by successful completion of the core courses PHAR 700 and PHAR 701. These courses are normally taken in the first and second semesters of the student's program within the Department of Drug Discovery and Biomedical Sciences but may be taken as late as the third and fourth semesters, depending on availability. The course examinations will constitute the written portion of the admission to doctoral candidacy examination. These examinations are maintained by the course coordinators or the Graduate Program Director.

Part II

Part II of the Admission to Candidacy consists of four different segments: selection of a research advisor, selection of the graduate committee, submitting a Program of Study form, and completing the IRP/qualifying examination.

Selection of a Research Advisor

A research advisor must be selected by **the beginning of the second year**. The student must notify the Graduate Program Director in writing of the faculty member selected.

Selection of the Graduate Committee

A graduate committee must be selected by **the end of the second year**. The student must consult with the research advisor prior to determining the composition of the committee and must also contact each prospective committee member to ensure that each faculty member is willing to serve on the student's committee. The student must then notify the Graduate Program Director in writing of the committee's composition using the G-DCA 'Doctoral Committee Appointment Request' form available at the USC Graduate School forms library website: https://www.sc.edu/study/colleges_schools/graduate_school/forms_library/index.php.

The graduate committee for the Ph.D. student will consist of at least five members and include the following:

- Research advisor
- A second member in the respective research field
- Two members in the DDBS department outside the research specialty area
- Member in a related area-from a different department/college ('Outside Member')

Committee members from outside the university may be included if it is considered useful or necessary. However, they must submit their Curriculum Vitae to the USC Graduate School for formal approval. Note that in the case of joint co-advisors, a minimum of six committee members is entirely possible but not required. If a committee member cannot attend a meeting, a substitute member will be appointed in consultation with the committee chair and Graduate Program Director. A revised G-DCA form is necessary if there is a change in committee members' makeup (e.g., a committee member moves to a different university).

Ph.D. Program of Study

The Program of Study must be completed by the end of **the second year**. Students must use the DPOS form 'USC Doctoral Degree Program of Study' available from the USC Graduate School (<u>https://www.sc.edu/study/colleges_schools/graduate_school/documents/doctoralprogramofstudy.pdf</u>). The Program of study is <u>one</u> <u>of the most important documents</u> related to the student's Ph.D. studies. This document is a contract between the student, the Department of Drug Discovery and Biomedical Sciences, and the University and ensures that successful completion of the courses listed in the document will satisfy the requirements for the Ph.D. degree. No additional courses can be added to or deleted unless the student agrees. The student must sign the Program of Study, as well as the major professor, and forward the document to the Graduate Program Director.

Submission of Initial Research Proposal (IRP)/written qualifying examination

Because a career in science involves submission of research proposals for critical review, the IRP provides an opportunity to engage in writing competitive applications. Graduate students are encouraged to apply as soon as feasible for independent research fellowship awards. For example, a Ruth Kirschstein NIH Training Fellowship (<u>https://researchtraining.nih.gov/programs/fellowships/F31</u>) or National Science Foundation (NSF) Graduate Research Fellowship Program (GRFP) award (<u>https://www.nsfgrfp.org</u>). Therefore, the proposal should be written in the style of an NIH proposal. The exam is composed of two parts: a written research proposal that reflects your plans for dissertation research and an oral defense of the work. The dates for each of these phases should be arranged in consultation with your advisor and the members of the Advisory Committee. Please also see the section titled "Guidelines for Written and Oral Proposals" for more detail.

The IRP/qualifying examination must be completed by the end of **the second year**. The topic of the proposal is the student's planned Ph.D. research project. The topic should be jointly selected by the advisor and the student. The graduate student is free to request copies of grant proposals submitted by their mentor and other resources such as examples of previously well-written student proposals to serve as models. However, the written proposal must be in their own words. The IRP must be distributed to the members of the committee at least <u>five</u> business days prior to the committee meeting. The student must then present the IRP to the Ph.D. dissertation examination committee and defend the proposal during an oral examination by the committee (see below).

The student must ensure that the committee chair notifies the Graduate Program Director in writing after the successful defense of the IRP.

Defense of the Initial Research Proposal (IRP)/Oral Qualifying Examination

To complete the Ph.D. Candidacy Process, the student's Ph.D. dissertation committee will convene at the request of the student. This is a closed meeting with only examination committee members. At the meeting, the committee will proceed to:

- 1. Elect a committee chair if one has not previously been designated. The chair of the committee will be a graduate DDBS faculty member, but not the student's major advisor.
- 2. Review the student's written candidacy exams (Part 1, exams in PHAR 700 and PHAR 701). The exam performance is obtained by the research advisor).
- 3. Review the Program of Study and academic record and receive input from the major advisor regarding the rationale for the courses listed.
- 4. Receive input from the major advisor regarding research performance and the basis for the IRP.
- 5. Assess the defense of the IRP. The defense of the IRP will begin with a presentation by the student (approximately 40 minutes). The oral examination following the presentation will further explore the student's understanding of the proposed research, and approach to the problem and potential difficulties. The committee may choose to ask questions as the presentation proceeds. The evaluation of the defense of the proposal will be based on the content of the IRP and on answers to oral questions presented to the student by the committee.
- 6. Recommend approval or disapproval of admission to candidacy following the defense of the IRP. The committee will further discuss and review all the student's candidacy achievements. The committee may subsequently recommend approval or disapproval of Admission to Candidacy based on the student's performance for all candidacy requirements. An affirmative vote of at least 75% of the graduate student's committee in attendance will constitute approval.

The committee may also at their discretion:

- Ask that a revised IRP be submitted for approval without further examination.
- Ask that a revised IRP be submitted for approval with a second and final oral examination.
- Place the student in the Master of Science program.
 - (NOTE: The student may petition to re-enter the doctoral program upon completion of the M.S. degree.)

Upon successful completion – recognized by signatures on the 'Doctoral Qualifying Exam Verification' form – it is the responsibility of the student to submit the final approved IRP and a copy of all signed documentation to the Graduate Program Director. The exam verification form is available at the following website:

(https://www.sc.edu/study/colleges_schools/graduate_school/documents/qual_exam_verification_fillable.pdf).

Finally, it is the responsibility of the Graduate Program Director to submit all required documentation to the USC Graduate School and place copies in the student's permanent file. The Dean of the USC Graduate School will notify the candidate of their admission to doctoral candidacy.

Please note: The USC Graduate School requires the student be in candidacy at least one year prior to graduation.

Comprehensive Oral and Written Examination

Following admission to candidacy and completion of all course work, a Comprehensive Oral and Written examination must be taken before the **end of the 3rd year** in the student's degree program. The examination is to be conducted by the student's graduate committee in an area outside of the student's immediate dissertation research focus. Such an exam aims to assess the knowledge and capabilities of a student before granting them a graduate degree. It is required that the student notify the Graduate Program Director at least two weeks in advance of when the meeting has been scheduled. The comprehensive exam requirement of the Graduate School is satisfied following the successful completion of the written research proposal.

Before the oral examination date, the dissertation advisor, in collaboration with the committee, will select three abstracts unrelated to the student's primary research focus. The abstracts are normally chosen from appropriate sources such as recent scientific conferences and may be on topics in which the advisor would like the student to become well versed. The three abstracts are given to the student on the morning of the examination. The student will select one abstract and leverage the conceptual information and data from the abstract to develop a new original hypothesis, outline specific aims, experimental design, expected results, and potential pitfalls to accomplish a novel independent project.

The student has from the time they receive the abstract (on or before 8 am the day of the exam) until the set meeting time, which must be at least six hours, to complete the task. At this time, the committee will convene for the student to present and defend the proposed project.

The student can present the project in any format desired (for example, Microsoft PowerPoint slides are acceptable) to defend the hypothesis and experiments that test the central hypothesis. The committee will ask questions as the presentation proceeds to explore the student's understanding of the proposed project, approach to the problem, and potential difficulties. The examination may also include questions concerning the student's didactic training. If a pass is issued for the oral portion of the examination, the student will have 2-7 days, as determined by the committee, to summarize the proposal in the form of an NIH or similar style research proposal and submit the written portion to each member of the comprehensive exam committee for evaluation. The written proposal should incorporate feedback the student received during the oral examination. The committee determines the length of the written portion of the comprehensive exam, but it is typically 3-6 total pages in length – and it is recommended that the student use the format at the end of this document. The committee chair will lead the exam evaluation, discussion and inform the student of the final decision. An affirmative vote of at least 75% of the committee is required for passage of the oral portion and the written portion of the comprehensive.

In the event of failure to achieve an affirmative vote of at least 75% of the committee members, the committee may recommend at its discretion:

- Minor revisions of the written proposal.
- Major revisions of the written proposal, potentially followed by a second and final oral examination.
- A second and final oral and written comprehensive examination.

Failure to successfully complete the comprehensive examination will normally result in a recommendation by the committee for transfer to the Master of Science program in Pharmaceutical Sciences. The chair of the committee will notify the Graduate Program Director in writing of the Committee's decision.

Upon successful completion of the comprehensive exam, the Graduate Program Director will submit the Doctoral Comprehensive Exam Verification form to the USC Graduate School and place a copy in the student's permanent file:

https://www.sc.edu/study/colleges_schools/graduate_school/documents/doc_comprehensive_exam_verification.pdf

Pre-defense committee meeting

Although Annual committee meetings will help to guide the dissertation work, it is recommended that a pre-defense dissertation meeting be convened for an update and discussion of a target completion date of the dissertation **approximately 6 months before the dissertation defense date**. This meeting is called by the graduate student in consultation with the dissertation advisor. The length of time needed for this meeting is typically one hour. It is recommended that an initial draft containing the proposed dissertation title, an abstract or summary, and proposed dissertation chapter titles be sent to the committee members prior to the meeting. The primary purpose of this meeting is to provide a framework of understanding for the advisor and student regarding aspects of the project that need to be completed to graduate from the program.

Dissertation

A written dissertation is required to complete the Ph.D. degree. The student is strongly encouraged to check the USC Graduate School guidelines <u>BEFORE</u> beginning to write the formal dissertation. Note that all theses and dissertations are officially submitted online to the USC Graduate School (<u>https://www.sc.edu/study/colleges_schools/graduate_school/academics/thesis_and_dissertation/index.php</u>). The student should start writing the appropriate parts of the dissertation (e.g., methodology) as soon as possible, and follow the formatting requirements of the USC Graduate School. Completed copies of the dissertation should be given to all graduate committee members *at least 10 working days* before the defense of the dissertation. Note: please be reminded to submit the intent to graduate form available in Self Service Carolina and meet all semester deadline dates for dissertation format and dissertation defense.

Dissertation Seminar and Defense

A dissertation seminar and defense must be completed within 8 years of the start of the Ph.D. program. The dissertation seminar and defense must be scheduled through the Graduate Program Director, following consultation with all committee members. The Graduate Program Director or the Graduate Program Assistant will be responsible for publicity and notification of college faculty for the scheduled dissertation seminar and defense.

The formal seminar is open to the public, including friends and family members. The student's presentation should last approximately 50 minutes, leaving 10 minutes at the conclusion for questions from the audience. The student and the dissertation committee will then adjourn to a private session for the second part of the exam. An affirmative vote of at least 75% of the graduate committee will constitute a passing performance. After successfully defending the dissertation, the student will need to complete any necessary revisions to the written dissertation and submit them to the dissertation committee for final approval.

Once final committee approval is obtained, a completed G-DSF (Dissertation Signature and Approval Form) must be submitted to the USC Graduate School along with a certificate of Survey of Earned Doctorate completion. Links to the G-DSF form and the survey are available in the USC Graduate School Forms Library.

In the event of failure to achieve an affirmative vote of at least 75% of the committee members in attendance, the committee may recommend at its discretion:

- Major revisions of the dissertation followed by a second and final defense of the dissertation within one year.
- A second and final defense of the dissertation is to be conducted within 90 days.

Failure in a second dissertation defense will normally result in a Master of Science degree in Pharmaceutical Sciences being awarded. In this case, the chair of the graduate committee will notify the Graduate Program Director in writing of the committee's decision – including the path forward agreed upon by the committee.

M.S. Degree Progression

An M.S. progress sheet has been developed for use by the Graduate Program to facilitate monitoring of the progress and status of each graduate student. The deadlines and requirements listed are mandated by both the College of Pharmacy and the USC Graduate School of the University of South Carolina and <u>must be completed before the M.S. degree will be awarded</u> by the USC Graduate School. If these requirements are not met in a timely fashion, progress towards completing the M.S. degree will be jeopardized. Summer school sessions are not counted in calculating the deadlines. If the student does not meet the deadlines in a reasonable manner, the Graduate Program Director will notify the student in writing, requesting details concerning how and when the headline(s) will be satisfied. The M.S. program must be completed within 6 years after enrollment in the degree program. Any course taken that is more than 6 years old cannot be used towards the completion of the degree.

Admission to M.S. Candidacy

All students must be admitted to Candidacy to pursue the M.S. degree. Admission to candidacy is a two-part process as follows:

Part I

Part I of Admission to Candidacy is satisfied by successfully completing the core courses PHAR 700 and PHAR 701. See also Part I of Ph.D. Degree Progression/Admission to Candidacy above for further details.

Part II

The second part of admission to Candidacy consists of 4 different segments as follows:

Selection of a Research Advisor

The selection of a research advisor must be completed by the end of the 2nd semester. See also Part II of 'Ph.D. Degree Progression/Selection of a Research Advisor' above for further details.

Selection of Graduate Committee

Must be completed by the end of the 2nd semester. See 'Ph.D. Degree Progression/Selection of Graduate Committee' for further details. The Graduate Committee for the M.S. student will consist of <u>at least 3 members</u> from the DDBS graduate faculty. <u>A chairperson for the Committee must be</u> <u>selected at this time.</u> The chairperson must be a committee member from the College of Pharmacy but cannot be the research advisor. Committee members are typically:

- The research advisor
- A second member in the specialty area
- A faculty member in DDBS outside the specialty area

M.S. Program of Study

A program of study must be submitted to the Graduate Program Director by the end of the 2nd Semester. See 'Ph.D. Degree Progression/Ph.D. Program of Study' for further detail.

Submission and Defense of Initial Research Proposal (IRP)

Must be completed by the end of the 3rd semester.

See 'Ph.D. Degree Progression/Submission and Defense of IRP' for further details.

Comprehensive Written Examination (towards the M.S. degree)

After admission to candidacy, a Comprehensive Written examination must be taken within <u>90 days of completion of all course work</u>. The exam will consist of questions involving previous course work and will be administered by the chairman of the student's committee. The committee chair will notify the Graduate Program Director in writing of the examination 14 days prior to the examination and request questions from all previous instructors. The examination will be numerically graded based on 100 points. The chairman of the student's committee is normally responsible for determining the exam's composition. Approximately 50% of the exam should come from the student's discipline. The chairperson will contact each committee member to determine the pass/fail status and forward this determination to the Graduate Program Director using the 'Admission to Candidacy' form. The student will be notified in writing of successful completion or failure of the examination. In case of failure, one re-examination is allowed within 30-90 days following the initial notification of results.

Thesis for completion of the M.S. degree

A written Thesis is required for completion of the M.S. degree. The student is strongly encouraged to check the USC Graduate School and College of Pharmacy guidelines <u>BEFORE</u> beginning to write the document. Note that all theses are officially submitted online to the USC Graduate School.

https://www.sc.edu/study/colleges_schools/graduate_school/academics/thesis_and_dissertation/index.php

The student is strongly encouraged to begin writing the appropriate parts of the thesis (e.g., methodology) as soon as possible and to follow the requirements of the USC Graduate School. Completed copies of the thesis should be given to all graduate committee members at least 10 working days before the defense of the thesis.

Thesis Seminar and Defense

A Thesis Seminar and Defense must be completed within 6 years of admission to the M.S. program. The thesis seminar and thesis defense must be scheduled by the Graduate Program Director, following consultation with the chairperson of the graduate committee. The Graduate Program Director and the Graduate Program Assistant will be responsible for all publicity and notification of college faculty for the scheduled thesis seminar and defense. The thesis seminar will typically be 40-50 minutes in length with appropriate visual aids and will be presented to all DDBS students, faculty, and scientific staff. Following the thesis seminar, the student will reconvene with the graduate committee in attendance will constitute a passing performance.

In the event of failure to achieve an affirmative vote of at least 66% of the committee members in attendance, the committee may recommend at its discretion:

• Major revisions of the thesis followed by a second and final defense of the thesis to be conducted within 30-90 days.

Failure in a second defense of the thesis will normally prevent the awarding of a Master of Science degree in Pharmaceutical Sciences.

Departmental Seminars

Philosophy and Objectives

There are two components of the departmental seminar program that contribute to graduate education. The first component consists of selected outside speakers invited by the College of Pharmacy. The objective of inviting outside speakers is to provide the students and faculty with an opportunity to interact with international experts on topics of interest in drug discovery, pharmaceutical and biomedical sciences.

The second component is attendance and participation in PHAR 712, which is offered during the fall and spring semesters. These seminars are presentations prepared by graduate students and presented to the graduate students and faculty. In this course, students gain valuable experience in preparing and delivering research seminars in front of an audience of colleagues. Please see the syllabus and course objectives for PHAR 712 for details. The collective goal of the seminar programs is to provide valuable experience in learning science and communicating science in a seminar format. Note that graduate students are required to attend all departmental seminars.

Graduate Student Research Activity and Expectations

Every graduate student in Drug Discovery and Biomedical Sciences is expected to maintain a vigorous research program. This is demonstrated through the submission of abstracts and presentation of posters and talks at national and international meetings, as well as participation in the preparation of manuscripts submitted for publication in peer-reviewed journals. The following are general expectations of Pharmaceutical Sciences graduate students:

- Contribute to maintaining an intellectually stimulating environment, emotionally supportive, safe, and free of harassment.
- Be committed to graduate education, demonstrated effort in the classroom, research, and other academic settings.
- Respect for others and understand that research space, equipment, and other resources are shared, and that care must be exercised, with problems reported as they arise.
- Be knowledgeable of the policies and requirements of the graduate program, the College of Pharmacy, and the University of South Carolina, and strive to meet these requirements, including meeting appropriate deadlines.
- Maintain a high level of professionalism, self-motivation, engagement, excellence, scholarly curiosity, and ethical standards.
- Continuously strive to be knowledgeable of past and current literature that influences the field of study.
- Balance duties and allocate professional time to be academically effective.
- Be responsive to the advice of and constructive criticism from the graduate committee.
- Discuss policies on academic work hours, sick leave, and vacation with the research advisor or the Graduate Program Director.
- Complete all pertinent laboratory, College, and University orientations and trainings such as human subject training, new graduate student orientation, safety training, and Title IX training.
- Acknowledge primary responsibility to complete the degree and develop a career following degree completion. The graduate student should seek guidance from the research advisor, thesis/dissertation committee members, career counseling services available at USC and the USC Graduate School, writing support services, and other mentors.

Manuscript(s) Requirement and Laboratory Notebooks

Laboratory notebooks and drafts of all papers to be published from the student's research project <u>must</u> <u>be submitted</u> to the major advisor before the Graduate Program Director will sign and approve the final Graduation Clearance form. The candidate <u>WILL BE BLOCKED</u> from graduating from the degree program unless a 'signed' Graduation Clearance form has been received by the USC Graduate School.

Laboratory Safety

Each graduate student is responsible for not only their own safety but also that of nearby co-workers. To enable a safe working environment, the Health and Safety Officer of the College of Pharmacy is responsible for monitoring and enforcing Environmental Health and Safety (EHS) Guidelines of The University of South Carolina. The guidelines require that each graduate student:

- Attend a Hazardous Waste Training course offered by EHS, as well as any annual online or live refresher training required. Read and sign the Chemical Hygiene Plan appropriate to the laboratory or laboratories in which the student will conduct research.
- Attend all other safety training course required for any aspect of the research projects, as well as any required refresher training required (see below).
- Become familiar with the MSDS sheets of the chemicals used.
- Wear safety glasses in areas where experimental work is being conducted.
- Should not wear contact lenses, due to risk of corneal abrasions in the event of an accident.
- Should conduct hazardous reactions and procedures only after proper consultation with the
 research advisor. It is expected that the student will become thoroughly knowledgeable about the
 potential hazards involved by reading the appropriate literature prior to the experiment, and have
 contingency plans ready in case of an accident. Potentially hazardous reactions should first be
 attempted on a small scale and only in the presence of other laboratory personnel who are aware
 of the type of experimentation and inherent dangers involved.
- Should be aware of the location of explosion-proof refrigerators.
- Should not store food in any refrigerator used for research purposes.
- Always wear appropriate shoes in the research laboratories.
- Be familiar with the location and operation of eye washes, safety showers, spill kits, and fire extinguishers.
- Should not leave experiments unattended. If it is necessary to leave an experiment unattended, the situation should be carefully checked beforehand to minimize the risk of:
 - Water leakage adjust H₂O pressure, secure all hoses, and clear all drains. Water should not be allowed to run at high velocity through condensers.
 - Vapor leakage make sure all joints are vapor tight and adequate water flow is available for condensation.
 - Electrical fires make sure all cords are intact and electrical equipment is in good working order.
- Should use radioactive isotopes only with the approval of the research advisor and under the
 appropriate authorization by the Radiation Safety Officer. All students working with radioactive
 isotopes are required to take the radiation safety training course provided by the University. All
 research work involving radioactive isotopes should only be performed in those areas designated
 for such experiments.
- Should perform experiments with mammalian cell culture, mouse or human tissues, or live animals only with the approval of the research advisor and after the appropriate training in biosafety and animal care in courses provided by the University. Any annual online or live refresher training is also required.
- All research work involving a biosafety risk (e.g., BSL-1, BSL-2), must be performed in areas designated for such work.
- Should not conduct unauthorized experiments Laboratory work outside the student's areas of research and without the proper approval of the research advisor is prohibited.

- Should properly dispose of all wastes according to department and University Environmental Health and Safety Guidelines.
- Should notify the research advisor immediately of any potential safety hazard or accident.

Guidelines for Written and Oral Proposals

The sections below provide guidance on the written examinations and oral examination meetings, including the responsibilities of the students, advisors, and committee chairs.

Guidelines for students in advance of all committee meetings and examinations

Beginning at least six weeks in advance, the student should communicate with committee members to arrange the date, time and location of the meeting. The student is required to communicate with the Graduate Program Director or administrative assistant to the graduate program, to inform them of the date, time, and place of the meeting, and to confirm all required paperwork is completed.

Conference rooms or classrooms typically available for meetings and examinations are CLS 313, CLS 510, CLS 010, and CLS 716, which may be reserved by contacting Ms. McKeown at (803) 777-0757 or <u>rachelm@cop.sc.edu</u>. The <u>student</u> is required to bring the <u>appropriate paperwork and forms</u> to the meeting. It is the student's responsibility to notify IT staff at least one week in advance of the actual meeting to arrange for any necessary computer, video and audio connection.

Guidelines for dissertation/thesis committee meetings and examinations

Meetings will typically begin with a brief introduction by the committee chair and the advisor. The student will usually be asked to leave the room for a short time. At this point, the advisor will comment on the student's progression and productivity in the laboratory. When applicable, the committee will discuss coursework grades and programmatic progression. The committee may also discuss elements of how an examination will proceed. For example, the committee member from outside the department may have specific questions regarding procedure, particularly for the format of the comprehensive examination. Once the student returns to the room, the meeting or examination will officially begin. The Chair of the Committee will typically moderate the examination and assure that each participant has adequate time to ask questions.

IRP/Qualifying and Admission to Candidacy examination

Students are required to bring the completed Program of Study document and the PhD/MS admission to candidacy form. The POS document will be discussed as part of the conversation at the start of the meeting. Review of all coursework is also part of the admission to candidacy. Once the examination begins, the student is encouraged to make a presentation of 30-40 minutes, leaving appropriate time for questions during the presentation. The presentation should follow the outline of the written proposal. A typical examination will take approximately two hours. At the conclusion, the student will be asked to step out of the room, and the committee will discuss the exam performance and make recommendations. Successful completion of the oral defense will be based on the student's grasp of the proposed research, on the student's understanding of theoretical and practical aspects of proposed research technologies, and on the student's familiarity with and ability to use knowledge from didactic courses and research experiences. As described previously, the committee may vote to pass, require a revised written document be submitted for approval without further examination, require that a revised written document be submitted for approval with a second oral examination, or recommend that the student be placed in the Master of Science program. The committee chair will provide a brief written summary of the strengths and weaknesses of the candidate. In instances that progression in

the Ph.D. program is not recommended, the committee chair will provide in the statement the reasons for the vote of the committee not to pass.

Comprehensive examination

For the comprehensive examination, the graduate student will usually begin by introducing which abstract was selected. The student can then present the proposed project in any format desired (usually Microsoft PowerPoint slides or equivalent; in addition to illustrating ideas on a whiteboard) to defend the hypothesis and experiments that test the central hypothesis. At the conclusion of the examination, the student will be asked to step out of the room, so that the committee can discuss the performance. Successful completion of the oral examination will be based on the student's grasp of the proposed research and on the student's understanding of theoretical and practical aspects of proposed research work. As described earlier, the committee may vote to pass, require a revised written document be submitted for approval without further examination, or recommend that the student be placed in the Master of Science program. The committee chair will provide a summary of the strengths and weaknesses of the candidate. In instances that progression in the Ph.D. program is not recommended, the committee chair will provide in the statement the concerns of the committee.

<u>Update and discussion of target completion date of dissertation - Variable, approximately six</u> <u>months prior to completion</u>

This meeting will typically be less than one hour in duration. The student will provide a brief presentation, approximately 30 minutes, to provide an update on their dissertation research progress, discussion of current hurdles encountered, and immediate research plans. Updates on manuscripts published, in preparation, submitted, or in revision should be discussed. Although the final decision is at the discretion of the advisor, this meeting will provide a framework of understanding for the advisor and student regarding aspects of the project that need to be completed in order to graduate from the program.

Format guidelines for the written IRP and comprehensive examinations

Written proposals should follow the format of a predoctoral fellowship application (e.g., the F31 application to the National Institutes of Health (NIH)). The following should be included: Title page, Abstract/summary, Specific Aims, Research Strategy (with subtitles for Significance, Innovation, and Approach), and References. NIH-style proposals written by students that do not follow these guidelines will be evaluated by the committee as a proposal submitted to NIH, i.e., sent back without being reviewed.

The following guidelines are designed to help with the writing of a research proposal that will serve as the basis for the oral phase of the Qualifying/IRP examination. Organize your proposal to answer these questions: what do you intend to do? Why is the work important? What has already been done? How are you going to do the work? Make your goal specific and clear and make the proposal easy to read. Emphasize the concepts as well as the methods. Focus on experiments that you can carry out in a period of 2-3 years.

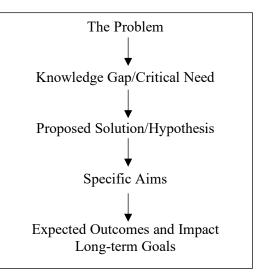
Be concise, yet complete, by including only those details that are essential. It is not necessary to give all the details of a procedure such as buffer compositions and exact incubation times. You should know these details, but in most cases, they need not be included in a proposal.

You should feel free to obtain advice from other students and faculty regarding the feasibility of experiments being proposed. However, this is your proposal and should include your ideas.

For general formatting, Arial font is recommended (11pt, single spaced) with at least 0.5-inch margins. Figures should be placed in-line with text with appropriate figure legends (Font Arial 9pt or greater). Please note that the committee may request larger spacing (double spaced or wider margins), but the page limit still applies for single spaced and 0.5-inch margins. For further guidance, sentences below in quotations are from NIH resources.

1. Specific Aims (One page limit).

Do the Specific Aims propose a clearly stated hypothesis that are logical extensions of preliminary work or the reports of others? The Specific Aims section should contain an introductory paragraph with a clearly stated problem, describe the gap in knowledge, a clearly stated hypotheses to be tested, and list of the Aims that will be performed to test the hypothesis. It is traditional to have two to four aims. The section should conclude with a few sentences that broadly describe the potential impact or benefit to human health from performing the project.



2. Research Strategy (single spaced, with the following suggested subsections)

a. <u>Significance</u>

How significant is the proposed work relative to the field? This section should provide background to explain the importance and relevance of the proposed research to understanding an aspect of human health and disease. Where possible, indicate how the study may result in the development of a new or improved therapeutic approaches to disease. The goal of this section is to entice the reviewer's interest in the project.

"Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?"

b. Innovation

This section should explain how the proposed research, if performed, will provide a 'jump', not an incremental step, in our knowledge of human health and disease.

"Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?"

c. Approach

Preliminary Studies/Progress Report

Grant proposals submitted to NIH contain a preliminary studies section for a new application, or a progress report for a competitive renewal application. These are very important sections. For the IRP, the student should consult with their major advisor regarding which preliminary data to include (e.g., potentially including data collected by others in the laboratory). Preliminary data can be included as a separate section under Approach, or as part of each separate aim. The comprehensive exam will not have preliminary data for the proposal because the project topic should be outside the

student's research area. However, the section should contain specific discussion of recently published information that help to shape the hypotheses and would therefore be considered 'preliminary data'. This is a separate section labeled, "Studies supporting the hypothesis".

Experimental Design

Although there are no specific recommendations on length, this section constitutes most of the proposal. The following subsections should be included for each Aim.

Restate the Aim as it was written in the Specific Aims section.

Rationale: There should be a 1-2 paragraph subsection that clearly states why the specific experiments are being proposed.

Approach: This subsection should describe the types of experimental strategies that will be performed. It should not be a "list" but should be written to build on the Aim. Most investigators include a section called "Anticipated Results" or "Data Analysis and Interpretation", which follows "Approach". Whether included within "Approach" or a separate subsection, <u>it is important that the student make predictions about the outcomes of the experiments being proposed.</u> What questions will be answered when the experiments are completed? The anticipated results should be related to supporting or refuting the central hypothesis.

Methods: This subsection contains experimental detail as to how the experiments will be carried out, much like a methods section in a journal article. Consider the feasibility of the work.

Potential Problems and Alternative Strategies: In this section, one tries to identify reasons why the experiments may fail and predict where a reviewer might criticize the work and provide a pre-emptive response. For example, are there alternative interpretations to your anticipated results? Alternative methods can also be included if there might be problems with the primary methods proposed.

It is customary to conclude this section with a subsection titled "Potential for Impact" or "Future Directions." This can be several sentences and should be similar in thought to the last sentences in Section A. If the research proposed is successfully completed, what might be next? Lastly, is the research proposed reasonable for a 4-year time frame? Or have you proposed 3 months or 15 years' worth of work?

"Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?"

3. References (no page limit)

The reference section does not count toward the length restrictions. Reference citations should include the full citation, i.e., author names, year, volume and page numbers, <u>and title</u> of the article, as per NIH guidelines.

Websites containing additional instructions and resources are provided below regarding how these components of NIH grants are reviewed:

https://www.niaid.nih.gov/grants-contracts/fellowship-grants https://www.niaid.nih.gov/grants-contracts/sample-applications http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html