

# Master of Science in Clinical Research

Student Handbook 2024-2025

# Division of Translational Science RUSH Medical College

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### **Overview of Academic Program**

The Clinical Research Master of Science program at Rush University offers a comprehensive pathway for both full-time and part-time students seeking to deepen their understanding and expertise in the field of clinical research. With options for completion in either five semesters full-time or eight semesters part-time, the program is designed to accommodate the diverse needs and schedules of its student body. While the program is particularly well-suited for medical doctors seeking to enhance their research skills, it also attracts individuals from various backgrounds who share a keen interest in clinical research and its implications for advancing healthcare practices and patient outcomes.

In this dynamic and interdisciplinary program, students delve into the intricacies of clinical research methodologies, ethical considerations, regulatory requirements, and data analysis techniques under the guidance of experienced faculty members. Through a combination of rigorous coursework, hands-on research experiences, and practical training, students gain the necessary skills and competencies to design, conduct, and analyze clinical research studies effectively.

One of the program's distinguishing features is its emphasis on thesis work, where students collaborate with faculty members to generate novel knowledge relevant to clinical research. Through this hands-on research experience, students have the opportunity to apply theoretical knowledge to real-world research settings, working closely with faculty on innovative projects that contribute to the advancement of clinical science. Whether partnering with healthcare institutions, analyzing data, or conducting clinical trials, students gain invaluable practical experience and develop professional networks that are integral to their academic and professional growth.

Throughout the program, faculty members provide mentorship and guidance to students, offering support and expertise to help them navigate the complexities of clinical research. Whether assisting with research project development, providing career advice, or facilitating networking opportunities, faculty play a pivotal role in supporting students' academic and professional growth.

Upon completion of the program, graduates are equipped with the skills, knowledge, and practical experience needed to excel in various roles within the clinical research field. Whether pursuing careers as clinical investigators, research coordinators, data analysts, or regulatory affairs specialists, graduates of the Master of Science in Clinical Research program are well-prepared to contribute to the advancement of medical science and improve patient care outcomes.

#### **Program objectives**

Students who complete the program will be able to carry out the following:

- 1. Demonstrate the ability to design and conduct clinical research, analyze data, and interpret results to answer a research question
- 2. Demonstrate the ability to read and critique the clinical research literature

3. Present clinical research findings (from literature and/or their own research) to peers

#### **Degree Requirements**

The program consists of three components:

- 1. Minimum of 32 graduate credits
- 2. A clinical research thesis project culminating in a written thesis
- 3. A public presentation and a private defense of the thesis

#### Curriculum

There is a core curriculum (21 credits) that is supplemented with thesis research (11 credits).

#### Coursework

Students are required to complete a total of 21 credits of coursework, including:

CRE - 561 Introduction to Epidemiology Credit(s): 2

GCC - 546 Principles of Biostatistics I Credit(s): 2

GCC - 548 Bioinformatics Credit(s): 1

CRE - 556 Clinical Research Design Credit(s): 4

GCC - 551 Ethics and IRB Credit(s): 2

CRE - 562 Advanced Epidemiology Credit(s): 2

GCC - 547 Principles of Biostatistics II Credit(s): 2

GCC - 549 Bioinformatics II Credit(s): 1

CRE - 500 Clinical Research in Practice Credit(s): 3

GCC - 594 Introduction to Grant Writing Credit(s): 2

#### Thesis

Please see Appendices for important information regarding the thesis.

Students complete a minimum of 11 credits of research, as outlined above. Students must enroll in CRE-597 from the summer term of the first year until graduation for one to nine credits per term, depending on their plan of study. While enrolled, students must complete thesis-related milestones and requirements that ensure the successful completion of the research project.

Students are required to complete and defend a data-driven thesis that provides a culminating experience and applies the principles and methods learned in the coursework to a real-life research project. The goal of the thesis is to demonstrate the student's understanding of the clinical research process from both a theoretical and a practical point of view.

With the support of the program director, each student must identify a research mentor and form a thesis committee. The student works closely with their mentor to develop their research proposal while they are completing their coursework in the first year. The research project must involve the analysis and interpretation of data. Students are encouraged but are not required to conduct primary data collection.

The primary thesis adviser in conjunction with the thesis committee will be responsible for guiding the student on the research idea, its practicality, feasibility, application and timeline for completion. Students must meet with their mentor and full thesis committee, including the program director, at least once every six months to provide a progress update and receive recommendations for moving forward to completion. The mentor and thesis committee are also responsible for reviewing and approving the thesis. Once approved, the student defends the thesis.

All students will be required to submit the thesis to ProQuest to be eligible for graduation. Specific formatting guidelines are required as set forth by the Center for Academic Excellence. All students are encouraged to formulate their original research into a scientific journal article and submit the manuscript as a publication in a peer-reviewed journal.

#### **Course of Study**

The Master of Science in Clinical Research program can be completed either part-time or full-time depending on the goals of the student. Courses will take place in person in the late afternoons or early evenings, supplemented with asynchronous online components. The program is designed so that a full-time student may complete their coursework in one academic year. Thesis research components of the program should begin as soon as mentors have been identified during the first spring semester in the program. All students must at a minimum be enrolled part-time (five credits) during the first year of the program to maintain active status in the Division of Translational Science (DTS). After completion of didactic courses, students in Thesis Research must enroll in a minimum of one credit to maintain active status.

#### **Educational Assistance Benefits (EAB) Funding**

RUSH employees can qualify for tuition reimbursement through the Educational Assistance Benefits (EAB) program, formerly known as LEAP. Contact your department administrator for EAB benefit and qualification information.

#### Master of Science in Clinical Research: Academic Policies

#### **Academic Standing**

Students must maintain a cumulative 3.0 grade-point average, earn a pass in courses with a pass/no pass option and meet the requirements of their program at the end of each term to remain in good academic standing. Any student who falls below this academic standard is academically deficient and not eligible for graduation. Failure to remediate deficiencies within one academic semester can result in dismissal by the DTS. Students who earn a C or below in a core course must retake the course.

#### **Program Time Limitations**

Students in the Clinical Research Program are expected to meet all requirements for graduation within five semesters (if enrolled full-time) but must graduate within eight semesters (if enrolled part-time) in the DTS. This period begins with the term in which the student formally matriculates into the program. Exceptions to the time limitation must be submitted to the DTS Advisory Committee in writing. The request must identify the reasons for the extension and provide a written plan with reasonable deadlines for completion. This document should be cosigned by the student's research adviser and program director. If the extension is approved, the student is expected to complete all milestones and program requirements. A second request may be made by the student's adviser and program director but may or may not be granted by DTS Advisory Committee. Following the second approved extension, the student must complete all requirements for the Master of Science degree or face dismissal.

#### Leave of Absence

The maximum length of accumulated Leave of Absence is 12 months. Requests for leave beyond the 12-month time limit must be submitted to DTS Advisory Committee in writing. The request must identify the reasons for the extent of leave and provide a written plan for return and revised deadlines for completion. This document will be co-signed by the student's research adviser and program director. If approved, the student must return at the time indicated on the initial request.

A second request may be made by the student's adviser and program director, but it may or may not be approved by the DTS Advisory Committee. Students must complete the university process to formally request a leave of absence.

Parental leave is granted in accordance with federal standards for students on federal grants, which is 2 months. Students should inform their program director in writing and request is granted through the program director.

#### **Division of Translational Science: Academic Policies**

The Division of Translational Science (DTS) follows University-wide policies and procedures and reviews program-specific regulations. However, the DTS reserves the right to make substantive changes in its programs after a student has matriculated. Students will be informed in writing if any requirements are changed. Students re-entering the college after an absence will be guided by policies and procedures in effect at the time of re-entry.

#### **Examination Policy**

The DTS maintains rigorous standards for course and examination policies to ensure academic integrity and consistency across all programs. These policies are essential to uphold the quality and fairness of the educational experience for all students. Specifically, the Course Director is responsible for distributing a course syllabus to all enrolled students at the beginning of each course. The syllabus must adhere to the format specified by the University Curriculum Committee and include detailed information on course objectives, content, schedule, assignments, grading criteria, and examination policies. All course and examination policies outlined in the syllabus must align with DTS guidelines. Course Directors must ensure that their policies are consistent with the Division's standards and provide a clear and comprehensive guide for students. All exams must be proctored to prevent academic dishonesty and ensure a fair testing environment. The Course Director must specify the procedures for proctored exams in the course syllabus, including the format, timing, and any special instructions. Proctors must be present during all exams to supervise students and enforce exam rules. The Course Director is responsible for arranging proctors and ensuring they are adequately trained to monitor exams effectively. Any breaches of examination policies or incidents of academic dishonesty must be reported immediately to the Course Director and handled according to DTS and university procedures. Students are expected to adhere to these policies, and any violations will be addressed according to the established disciplinary procedures.

#### Pass/No Pass Grades

Each program identifies all courses required of its students. Required courses are usually taken for letter grades (grades are A, B, C or F), although some may be offered as pass/no pass (P/N) option with approval from program directors. Research hours are graded using the P/N option.

#### **Good Academic Standing**

The University Rules for Governance defines good academic standing conditions. To remain in good academic standing, students must earn a B (3.0) or better in core courses, meet the requirements of their program and maintain a cumulative 3.0 GPA. Students should refer to their program academic policies for additional guidance on academic standing. Students who fail to remediate their deficiencies within one academic term, or are placed on probationary status a third time, are subject to dismissal by the DTS.

#### **Academic Probation**

Probationary conditions are defined in the University Rules for Governance.

The Registrar's Office will notify the Program Director when a student's cumulative GPA falls below 3.0. The Program Director will then email the student with a confirmation receipt to inform them of their change in academic standing to probation, followed by an in-person meeting.

If a student fails to meet other program requirements, the Program Director will notify the Division Head. The Division Head will inform the students by email with confirmation of receipt of their change in academic standing. This correspondence will be included in the student's permanent file.

#### **Dismissal**

Students can be dismissed if they fail to meet program requirements or go on academic probation for a second time. As the University Catalog outlines, students may be dismissed for academic misconduct or non-academic reasons. Procedures follow the University Rules for Governance as applies to the DTS. Dismissal decisions are made in consultation with the Program Director and the DTS Advisory Committee, and the student must receive adequate notice of such an impending decision. Letters of Dismissal or Administrative Withdrawal will be provided by the Division Head.

#### **Full-time Enrollment**

All DTS students must be enrolled full-time, except those Master of Science in Clinical Research students who request part-time enrollment. Full-time students must register for at least nine credits each term or at least 2 credits when enrolled in thesis and dissertation research courses. At time of graduation, the student must be enrolled in the college.

#### Residency

The Master of Science in Clinical Research program is a residential program may be part-time or full-time. The full-time Master of Science in Clinical Research students must graduate within five semesters. Part-time Master of Science in Clinical Research students must graduate within eight semesters. If a student surpasses these time constraints, they must formally request an extension for graduation. This request must identify the reasons for the extension and provide a written plan with reasonable deadlines for completion. This document will be co-signed by the student's advisor and Program Director and submitted to the DTS Advisory Committee. The DTS Advisory Committee will then vote on whether to accept the extension or not (passed by a simple majority). If the request is rejected, the student can submit an appeal as outlined below. Following the approval of the extension, the student is expected to fulfill all remaining requirements within the time limit defined in the extension permission. A subsequent extension request may be submitted by the student if necessary—the financial ramifications of the extension need to be determined before the request is approved.

#### **Students-at-Large**

Individuals with an accredited bachelor's degree or its equivalent have the option of taking select DTS courses as a non-degree student, prior to application to a degree program. The policy regarding the transfer of student-at-large credits can be found in the Rush University Academic and Institutional Policies section of this catalog.

#### Readmission

Any student who has voluntarily withdrawn from the University may apply for readmission by applying to the DTS. The student will pay tuition and fees at the rates in effect at the time of reenrollment.

#### **Academic Progression**

Students are responsible for understanding the requirements for academic progression and adhering to the criteria at the time of their enrollment in their Program.

#### **Student Academic Appeals Policy**

Any student of the DTS may appeal a final course grade, failure on a comprehensive or candidacy examination, or failure of the thesis/dissertation defense. A student may also appeal an unreasonable delay in their graduation from the University. A student may appeal a Dismissal or Administrative Withdrawal as stated in the University Rules for Governance. Course grades can be appealed directly through the Course Director. Comprehensive or candidacy exam failures, failure of a thesis/dissertation, and dismissal for other reasons can be appealed through the DTS Advisory Committee following the steps below:

- 1. The student must initiate the appeal process within fourteen (14) calendar days of the event that precipitated the appeal. The student will submit a written statement to the DTS Advisory Committee requesting consideration of their case. The student must provide the following in the written statement:
  - a. Cause for probation or dismissal, e.g., failure of thesis/dissertation.
  - b. Action being requested.
  - c. Justification for the request.
  - d. An outline of the efforts and actions already taken to obtain consideration of the request.

Copies of this written statement must be sent to the Program Director and the thesis/dissertation committee Chairperson as appropriate.

2. The Head of the DTS will instruct the Advisory Committee to convene an appeals committee comprised of non-conflicted voting members of the Advisory Committee. The appeals committee will include a student representative from a program different from the appealing student. Suppose a member of the Advisory Committee is conflicted, in that case, that member may be replaced with a non-conflicted faculty who is not a

member of the Advisory Committee. Faculty considered conflicted include the student's Program Director and those evaluating the student's academic status. Conflicted faculty will not be on the appeals committee but can be invited to present to the committee. The appeals committee will meet within fourteen (14) days of receiving the student's written request to appeal. The appeals committee will submit a report with a recommendation to the Division Head within five working days of the committee's meeting.

3. Within fourteen (14) days of receiving the appeals committee's recommendation, and upon discussion with the student and others as appropriate, the Division Head shall reach a final decision and notify each party. The conclusion reached by the Division Head is final. A designated appeals committee member will document the discussions and outcomes of all meetings in this appeal process. At any step in the process, the student may withdraw the appeal by written notification to the DTS Advisory Committee with a copy to the Division Head. In the event of a dismissal decision, a student may continue to enroll until the appeal process is completed or the student withdraws the appeal.

#### **Academic Honesty and Student Conduct**

The DTS and its programs follow the University policies on academic honesty and the university statement on student conduct. Each student is expected to conduct themselves at all times in a professional manner — a manner that conforms to the ethics of the profession and which instills confidence in one's abilities as a working scientist. Irresponsible, unprofessional or unethical behavior, as determined by Rush University honor code may result in dismissal from the program. The college and its programs will not condone cheating in any form. Allegations of cheating will be reviewed by the program director following internal DTS policies. If merited, the report will be forwarded to the Dean of Rush Medical College.

#### Use of Social Media and Artificial Intelligence

Students are expected to adhere to Policy Numbers OP-0362 and UAC-0039 requirements regarding the use of social media and artificial intelligence, respectively, in a way that is consistent with the parameters of responsible use as specified in the Policy.

# **Rush University Academic and Institutional Policies**

For additional information regarding any of the following, please refer to the Rush University Academic and Institutional Policies at

http://catalog.rush.edu/content.php?catoid=17&navoid=1522

- Enrollment
- Registration
- Continuous Enrollment/Active Student Status
- Withdrawal/Leave of Absence
- Incomplete Grades
- Students at large
- University Honor Code
- Diversity, Equal Opportunity, and Inclusion
- Rush's Policy Prohibiting Discrimination, Harassment and Sexual Harassment
- University Student Refund Policy
- Student complaint policy
- Health and Immunization Requirements

# **Appendix 1 Division of Translational Science Contacts**

Lena Al-Harthi, PhD

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Head, Division of Translational Science Professor and Chair of the Department of Microbial Pathogens and Immunity Vice Dean of Research

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Vice Head, Division of Translational Science Professor, Department of Microbial Pathogens and Immunity and Orthopaedic Surgery

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Katherine Powers, MS

Katherine Powers@rush.edu

Manager, Center for Academic Excellence

Registrar's Office Registrars\_Office@rush.edu

# Appendix 2

#### Division of Translational Science – MSCR Program Forming a Thesis Advisory Committee

#### **Requirements**

- The proposed composition of the Thesis Advisory Committee must be submitted to program director for review and approval.
- Committees are comprised of a minimum of three (3) members:
  - o Two (2) must be faculty at Rush University or John H. Stroger Hospital (with faculty appointment at Rush). This includes the Primary Thesis Advisor.
  - One (1) other can be internal or external
- All voting members of the Thesis Advisory Committee must be faculty members at an academic institution. An individual who is not a faculty member but could provide expertise relevant to the student's project may serve, but only as a non-voting member of the committee (i.e., ex-oficio).
- Upon approval, the student must submit the completed list to the manager of research and faculty affairs of DTS to keep in the student record within the division

#### **Guidelines for a Strong Thesis Committee**

In addition to the above requirements, the program director will weigh other factors to determine if the committee composition is appropriate for the student. These include:

- Representation of faculty with expertise in the student's study area(s) of research.
- Breadth of the committee as indicated by the inclusion of faculty whose primary expertise lies outside the student's major area of research.
- Breadth of the committee as indicated by inclusion of Medical College faculty from outside the student's program.
- Familiarity of the included faculty with the requirements and policies of the Medical College and the student's program.
- Availability of the faculty for regular committee meetings. At least three committee members are required to meet a quorum of the committee (three members or more) once every six months.

## Appendix 3

# INSTRUCTIONS FOR PREPARATION OF THE THESIS OR DISSERTATION

(The term "thesis" is used throughout this document, but the instructions apply to both theses and dissertations)

#### BASIC REQUIREMENTS

The three most important requirements for preparation of the thesis are:

- The thesis must be an original document written by the student.
- o The thesis must be clearly written, grammatically correct and free of typographical errors.
- Students may not simply bind their publications together in lieu of writing a thesis, but material from their previous publications or the work of others may be included if it meets the requirements below.

Students are encouraged to contact the Center for Academic Excellence (CAE) well in advance of submitting the thesis if they have questions. Students should review the CAE Rush Formatting Manual here <a href="https://www.rushu.rush.edu/rush-experience/student-services/center-academic-excellence/cae-manuals-handouts-and-tools">https://www.rushu.rush.edu/rush-experience/student-services/center-academic-excellence/cae-manuals-handouts-and-tools</a>

#### Inclusion of material previously published by the student

The spirit of the thesis is that it is the student's own work, which can be complex in this age of team science. Work taken from publications authored or co-authored by the student may be included in the thesis, but the following rules apply:

Keep in mind that the student's Advisor will be asked to attest on the *Results of Defense* form that the student contributed substantially to any text or figures included in the thesis.

If the thesis includes text or a figure which is part of the student's publication but the work was done by someone other than the student, permission must be obtained from the individual and explicitly noted (e.g., "Used with permission...") in the text or figure legend, as appropriate, and the role played by the other individual must also be clearly acknowledged in the text/figure legend.

The *Introduction* (first chapter) and *Discussion* (last chapter) of the thesis must be the student's own work and **not taken verbatim** from any publication.

Materials and Methods and Results sections may include text and figures taken verbatim from the student's previously published work. The complete reference and permission of the copyright holder to use the material must be cited.

Students may use their publication(s) to form the basis of a chapter(s) -- the following rules apply:

Note at the start of the chapter "This chapter is based upon (insert full citation)" and cite the
permission of the copyright holder (usually the publisher of the journal) using the language
provided by the journal.

- The text must be modified to the same style as the rest of the thesis there should be good continuity (i.e., flow) between all chapters of the thesis and between each section of a chapter.
- It is permissible to include text from the publication's *Introduction* and *Discussion* in the chapter (note that this is different from the *Introduction* and *Discussion* of the thesis, which must be the student's own work and not taken verbatim from any publication, as mentioned above).
- The student is responsible for obtaining any necessary permission that is required to use previously published work. Journals' websites will likely provide specific guidance for obtaining such permission. Please note that this process may take several weeks.

#### **Inclusion of the published work** *of others*

Textual material taken from publications *not* authored by the student may be included if it is indented 1/2 inch from the left margin, single-spaced, and properly referenced at the end of the text and in the bibliography.

Any reproduced text should generally be limited and have a clear purpose other than substituting for text that would normally be expected to be written by the author of an original thesis.

Figures from the work of others also may be included if clearly indicated and referenced in the figure legend.

The student is responsible for obtaining any necessary permission to use figures or text from the copyright owner and submitting it along with the thesis.

# Appendix 4

#### THESIS/DISSERTATION APPROVAL SHEET

The undersigned have examined the dissertation entitled (*Thesis title here in italics*) by (Your name here), a candidate for the degree of (degree here), and hereby certify that, in their judgement, the thesis is worthy of acceptance.

XXXXXX

Committee Member

Rank Dept

**Rush University** 

XXXXXXX

Committee Member

Rank Dept

Rush University/Other

XXXXXX

Committee Member

Rank Dept

Rush University/Other

XXXXXXX

Committee Member

Rank Dept

Rush University

XXXXXXX

Rank

Committee Member

Dept

Rush University/Other

Committee Member

Rank Title

Dept

Rush University/Other

Dr. Cynthia Brincat Dean, Rush Medical College Rush University