

PhD in Clinical and Translational Science Program Handbook

University of Pittsburgh
School of Medicine
Institute for Clinical Research Education

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PREFACE

Welcome to the PhD in Clinical and Translational Science Program of the University of Pittsburgh School of Medicine. This handbook provides information about the policies and procedures pertaining to the programs, the School of Medicine, and the University of Pittsburgh. Although the material contained within the handbook is reviewed and updated once a year, changes may occur during the year and are announced in memos, on the website, and by e-mail so that students are notified in a timely manner. All questions and suggestions concerning the handbook should be directed to:

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II. Program Overview

A. Mission

The Institute for Clinical Research Education (ICRE), in collaboration with the Clinical and Translational Science Institute, developed the PhD program in Clinical and Translational Science as a rigorous, advanced training program, designed primarily for clinicians, that builds and enhances the capabilities of trainees to conduct high quality clinical and translational research. The program has several unique and important attributes:

- The training program is highly multidisciplinary, in that its faculty and students span not only disciplines, departments, but also multiple schools of the health sciences.
- The curriculum is diverse and draws upon biostatistics, clinical research methods, and laboratory- and population-based sciences.
- The program concentrates on the conduct of clinical and translational research and requires the planning, execution and completion of an independent research project by each PhD student.

B. Objectives

The overall goal of the doctoral program in clinical and translational science is to produce the next generation of multidisciplinary academic leaders who will develop innovative research careers that will apply combinations of basic, clinical, and population sciences to the current problems of health and medical care.

The main objectives include:

- Teach students advanced knowledge of research concepts that enables them to conduct innovative independent research involving patients or material related to patients that is scientifically sound, ethical, culturally sensitive, and contributes to the improvement of human health and health care.
- Provide students with the skills to master a body of research knowledge that allows them to develop, present, and defend a novel research idea in the form of an NIH proposal format.

III. Program Admissions

A. Requirements for Admission

Admission to the PhD in Clinical and Translational Science is based on the total record of academic accomplishments. Evaluation of prior research experience, coursework, standardized scores, and letters of recommendation are components of the admission process. Applicants should have:

- Prior research experience
- A grade point average (GPA) of at least 3.5 in prior coursework
- GRE or MCAT scores (more details found in 6)
- TOEFL scores for those whose native language is not English (more details found in 6)

The PhD in Clinical and Translational Science program accepts candidates with an advanced clinical degree (MD, DMD, PharmD, etc) or those enrolled in clinical professional doctoral degree programs. Candidates with a baccalaureate degree, but not enrolled in an advanced clinical degree may be considered.

B. Application Process

All individuals applying to the Clinical and Translational PhD program must submit a complete application, including all requested information. The admissions committee will begin reviewing complete applications in December and continue to review applications until March/April. Selected applicants are invited to the University of Pittsburgh to be interviewed by members of the admission committee. Applicants will also have an opportunity to meet with other graduate students and prospective mentors. International applicants may be interviewed by telephone. Decisions will begin to be announced in January and continue until April. There is no application fee at this time.

Applications are due no later than April 15. Applications will not be considered or reviewed until all required materials are submitted. Failure to complete the application and include all requested material will result in the application not undergoing review.

All individuals applying to the Clinical and Translational Science PhD program must use the following procedures for preparing and submitting an application:

1. Online Application:

Applicants must complete an online application form found at:

www.icre.pitt.edu/phd/admission_process.html

A CV must be included as an uploaded file with the application.

2. Personal Statement:

Applicants must submit a personal statement that provides a detailed description of their research interests and relevant experience in research and their knowledge base in medicine, healthcare, and the healthcare delivery system. Additionally, the personal statement should describe how the program of study would help them enhance their ability to achieve career goals and conduct independent investigator-initiated research in their

area of interest. (1 page maximum). The personal statement can be uploaded with the on-line application.

3. Description of Research Experience:

Applicants must provide a brief description of their previous research experience. This description should include undergraduate and graduate research, research supervisors for each project, the technical and/or methodological skills that were acquired, and the hypotheses that were examined in the research. (2 pages maximum). The description of research experience can be uploaded with the on-line application.

4. Official Transcripts:

Applicants must submit official transcripts from all college or graduate level institutions attended.

5. Letters of Recommendation/Reference:

On the online application, applicants must provide the names of their department chair or division chief and two faculty members who have supervised your prior research and/or can attest to your academic credentials and potential as an independent investigator. These references will be sent e-mails containing their username and password with which to access an online evaluation form. They will complete a standardized evaluation checklist and will be asked to upload a formal letter of recommendation. In addition, applicants can optionally provide the name of a University of Pittsburgh mentor (if a mentor has been identified).

6. Test Scores:

The program strongly encourages every applicant to submit GRE scores for admission into the program. For applicants who hold an MD or DMD degree or are enrolled in a professional doctorate program, MCAT or DAT scores as an alternative standardized test score to the GRE. Any applicants who have completed an MD and are practicing physicians must submit complete scores from the LCME licensing exams. If the applicant is a member of a specialty board, documentation of specialty board examination must also be submitted.

Applicants who hold an MD (or professional dictate equivalent) from a non-US University will be strongly encouraged to take the GRE. If a non-US graduate does not have GRE or MCAT scores, they will be required to submit USMLE and ECFMG scores as evidence of capability on standardized exams. Applicants whose native language is not English are required to take the Test of English as a Foreign Language (TOEFL).

Test score criteria:

- GRE scores below a 500 in either the verbal or the quantitative category or below a 4.5 in analytical writing will raise serious concerns about the applicant.
- If the GRE, MCAT or DAT scores used to gain entry into a graduate professional program are too old to be officially reported from the testing agency, photocopies

may be submitted and a waiver will be requested (but not guaranteed) from the Office of Graduate Studies.

- A USMLE score below the 85th percentile or, for those who have taken the test after January 1, 2007, a score below 75, raises serious concerns about the applicant.
- Students taking a version of the TOEFL must score a minimum of 600 on the TOEFL pBT, a minimum of 250 on the TOEFL cBT, or a minimum of 100 on the TOEFL iBT. The scores of students taking the IELTS must be a band 7.0 or better.

All standardized test results and transcripts must be submitted in original form. The University of Pittsburgh code for the TOEFL, and GRE is 2927.

Transcripts and test scores can be mailed to:

PhD in Clinical and Translational Science
University of Pittsburgh
Institute for Clinical Research Education
200 Meyran Ave, Suite 300
Pittsburgh, PA 15260
Phone 412-586-9632
Fax 412-586-9672

C. Transfer Students

Students who wish to transfer from other universities may apply for admission and must meet the requirements described in section III.A. The number of credits that can be applied to the PhD in the Clinical and Translational Science program will be evaluated and determined by the Directors of the PhD Program Committee, then submitted to the Associate Dean for Graduate Studies in the School of Medicine for final approval.

Students who wish to transfer from other programs within the University of Pittsburgh or other programs offered by the ICRE at the University of Pittsburgh may apply for admission to the program and must meet the requirements described in section III.A. The number of credits that can be applied to the proposed PhD program will be evaluated and determined by the Co-Directors of the program, then submitted for final approval by the Associate Dean of Graduate Studies in the School of Medicine

In accordance with University policy, at least 36 credits toward the PhD degree must be credits obtained at the University of Pittsburgh. Students in the PhD program may transfer a total of 42 credits of graduate-level coursework from another graduate program but only 30 (with a "B" grade or better) of the 42 credits can be applied to the PhD in Clinical and Translational Science.

A candidate who has received an MS in Clinical Research at the University of Pittsburgh may apply up to 30 credits toward the PhD in Clinical and Translational Science. A candidate who has received a Certificate in Clinical Research at the University of Pittsburgh may apply up to 15 credits toward the PhD in Clinical and Translational Science.

D. Student Requirements and Expectations

A guiding principle of curriculum for the PhD in Clinical and Translational Science is that students will simultaneously engage in didactic coursework and practical, mentored research experiences. Coursework will be sequentially divided into required courses and selective/elective courses in the student's area. Students will begin participating in mentored research and developing their own research projects from their first semester. This requirement reinforces the thematic elements of the required and concentration area courses and exposure to practical and logistic research issues that can never be fully understood from didactic training alone.

Each student is expected to meet certain curriculum and program expectations and milestones throughout the program. The expectations and milestones are:

1. First Year Student

By the end of year one, the student must:

- receive approval from the primary mentor and Doctoral Program Committee of a 2-3 page research prospectus that includes specific aims
- have a research plan, including specific aims for research and undergo a preliminary evaluation.

2. Second Year Student

By the end of year two, the student must:

- establish a comprehensive examination committee
- undergo a comprehensive examination
- submit a comprehensive examination report.

3. Third Year Student

By the end of year three, the student must:

- form a dissertation committee
- prepare and submit a dissertation prospectus proposal
- schedule a prospectus overview meeting (present dissertation prospectus proposal)
- submit a dissertation overview report
- file for admission to candidacy.

4. Subsequent Years

Following year three, the student must:

- complete the dissertation project, which includes writing and revising the dissertation and making an oral defense
- apply for graduation
- schedule, announce, and present an oral dissertation defense

The table in section III.E gives a visual presentation of the curriculum expectations and milestones. A more detailed explanation of the curriculum can be found in section III.F and milestones in section III.G.

E. Overview of PhD Curriculum and Milestones

	Research Year 1		Research Year 2		Research Year 3		Subsequent Years
Summer	Measurement (1 Credit)	Preliminary Examination	Laboratory Methods (2 Credits)	Comprehensive Examination	Prospectus Overview (3 Credits Minimum)	Admission to Candidacy	**Dissertation Research (1-10 credits)
	Computer Methods (1 Credit)		Translational Research (2 Credits)		**Dissertation Research (1-10 credits)		
	Biostatistics (4 Credits)		Research Specialization Combination of directed research or elective coursework (24 Credits)		**Dissertation Research (1-10 credits)		
	Intro to Clinical Research Methods (3 Credits)						
Fall	Research Design and Development (Grant Writing) (5 Credits)						
	*Advanced "Selectives" (4 Credits)						
Spring	Research Ethics (1 Credits)						Dissertation Defense
	*Advanced "Selectives" (6 Credits)						

*6 Advanced "Selectives" credits must be Analytic Methods, 4 credits must be Clinical Research Methods

** Dissertation research must total 18 credits.

Shading Key:

Analytic Methods	Research Specialization Courses	Dissertation Research
Clinical Research Methods	Prospectus Overview	Dissertation Defense
Multidisciplinary Methods		

F. Curriculum

1. Credit Requirements

The doctoral program is (at minimum) a 72 credit program designed for full-time study. Students may be enrolled on a part-time basis. A minimum of 36 credits must be completed at the University of Pittsburgh.

2. Required Core Courses

The required analytic methods courses (6 credits) provide critical methodological, biostatistical, and measurement training for students. They are designed to prepare students to do the following: read academic and research literature critically and with an understanding of most statistical and measurement approaches being employed; conduct and interpret basic statistical analyses from their own or others' data; and collaborate fully with biostatisticians to plan and conduct statistical analyses related to their projects.

Required analytic methods courses are:

CLRES 2005	Computer Methods for Clinical Research	(1 credit, summer)
CLRES 2020	Biostatistics: Statistical Approaches in Clinical Research	(4 credits, summer)
CLRES 2040	Measurement in Clinical Research	(1 credit, summer)

The required clinical research methods courses (8 credits) focus on basic research methods, grant writing, and project presentation. These courses provide basic tools that will teach students to write proposals, conduct high-quality research, and disseminate their findings through presentations and journal manuscripts.

The summer core coursework is followed by a grant writing course, which is done through a two seminar series—the Research Design and Development Series and the Ethics and Regulation of Clinical Research Series—that build on the skills introduced during the summer. In these seminar series, the students learn how to develop a research question into an NIH-style grant application and how to identify important human subject protection issues and prepare an Institutional Review Board protocol. The final product is a completed grant application that follows the PHS-398 application format.

The required clinical research methods courses are:

CLRES 2010	Introduction to Clinical Research Methods	(3 credits, summer)
CLRES 2070/2071	Research Design and Development (Grant Writing)	(5 credits, fall/spring)

The required multidisciplinary methods courses (5 credits) are designed to provide training in the ethical conduct of research; in the conversion of research findings into behavioral, process, or system changes; and in the basic laboratory activities that enhance abilities to collaborate with bench researchers. The student must take CLRES 2050, but take the remaining credits from other courses they feel fit the category. The advisor must approve the selection.

The required multidisciplinary method course is:

CLRES 2050 Ethics in Regulation of Clinical Research (1 credit, spring)

Each student must take 10 Advanced "Selectives" credits. (6 credits of Analytic Methods and 4 credits of Clinical Research Methods) Courses can be taken from the ICRE course offerings or other PhD level course offerings in the Schools of the Health Sciences. Advanced methodology selectives must be approved by the students PhD advisor before enrollment.

Each student must take 24 Research specialization elective credits. These credits can either be directed research credits (not dissertation credits) or coursework selected by the student and his or her mentor and approved by the students PhD advisor. Research specialization elective credits are designed to allow students maximum flexibility in selecting training experiences in areas specific to their research area.

Students may register for some University of Pittsburgh courses over multiple semesters with approval from their mentor and advisor.

3. Directed Research and Independent Study Courses

Students may work with their mentors to design a Directed Research or Independent Study Course. Directed Research and Independent Study Courses require pre-approval from the PhD Committee and will only count toward Research Specialization credit requirements.

Students must complete and submit to a Program Coordinator a PhD Directed Research / Independent Study form no later than two weeks before the end of the registration period. Directed Research and Independent Study courses may only be from 1 – 3 credits. Courses must be completed within the semester they are approved for.

Students can only enroll for up to 6 credits of Directed Research and Independent Study coursework in any one semester and should not exceed a total of 12 credits of Directed Research and Independent Study coursework in their curriculum.

4. Dissertation Credits and Graduation

Doctoral students must register for at least 1 credit of Full-Time Dissertation Research (FTDR) in the 12-month period preceding defense of their dissertation and be registered for at least 1 credit of FTDR during the term in which they graduate.

A waiver of the requirement to be registered during the term of graduation may be granted by the School of Medicine Assistant Dean of Student Affairs. Only students who have earned at least 48 credits beyond a Master's degree or have passed the comprehensive examination may register for FTDR.

5. Research Training

Critical reading: Students are encouraged to obtain explicit training in critical reading of the research literature in their area of interest through participation in a monthly “journal clubs” offered by their home department or department related to their research area.

Oral presentation of research: Students are encouraged to give at least one public research presentation each year preferably at a national conference.

Seminars: Students are encouraged to attend any seminars that are sponsored or advertised by the ICRE. Center for Research on Health Care Health Services Research Seminars are held weekly from September to June. Students are expected to attend as many as possible. Email notices of these seminars will be sent regularly.

6. Mentored Research

Students will begin participating in mentored research and developing their own research projects beginning in Year 1. The goal of having students engage in mentored research early in the program is to ensure that they are actively participating in planning data collection, gathering data, and analyzing results while they are completing the didactic training that complements these activities.

7. Teaching Requirement

The PhD in Clinical and Translational Science requires that students fulfill a teaching assignment while completing the PhD in Clinical and Translational Science. To fulfill this requirement, students will serve as a Teaching Assistant (TA) for CLRES 2010 or an equivalent core course(s).

TA responsibilities include:

- attending class
- becoming experts in the assigned readings and topics covered in class
- advising MS and Certificate students
- offering recitations sections
- grading students’ assignments.

During the TA assignment, students will serve as the primary lecturer in the course for 1-2 sessions per members, (under the direct supervision of the course director). Primary lectures will be videotaped and analyzed with the student receiving feedback on their lecture.

For the semester in which the PhD student serves as a TA, they will be compensated for their time based on the hourly TA rate established by the University of Pittsburgh.

G. Program Milestones

1. Preliminary Evaluation

At the end of Year 1, each student will undergo a preliminary evaluation to ensure that he or she is meeting all of the program milestones. The evaluation will be conducted by the PhD program Co-Directors in conjunction with the student and his or her primary mentor. The evaluation will

involve a review of the student's academic and research progress and will lead to one of three outcomes:

- The student is making satisfactory progress and is allowed to continue with the program.
- The student is not making satisfactory progress and is placed on probation. Students on probation will be asked to work with their mentors and the program Co-Directors to develop a plan and timetable for remedial work that must be completed to achieve a satisfactory status.
- The student is not making satisfactory progress and is terminated from the program.

2. Comprehensive Examination

After a student has completed all of the core and selective coursework (typically by the end of Year 2 but no later than the first semester after the completion of the coursework), the comprehensive examination should be scheduled with the PhD Student Services Coordinator.

The goals of the exam are to:

- Assess the student's understanding of the three major areas of the curriculum (analytic methods, clinical research methods, and multidisciplinary methods) in the student's specific content area that is reflected by the student's advanced electives and research topic.
- Assess the student's ability to apply that knowledge to answer specific research questions in clinical and translational science.

Written Portion

The written portion of the comprehensive exam will follow the format of an NIH R01-style proposal and will include, at a minimum, specific research aims, background and significance, and research methods.

The topic of the examination will be selected by representatives of Doctoral Program Committee and at least 1 of the student's research mentors. Suggestions for the topic of the proposal may come from the student, but the final decision to accept, modify, or reject the selected topic will rest with the Doctoral Program Committee. Once the topic has been selected, the student will have 1 week to submit draft aims. Once the aims are approved, the student will have 8 weeks between the selection of the comprehensive topic and submission of the 10 page proposal.

Oral Portion

The student must schedule an oral defense of the comprehensive exam through the PhD Student Services Coordinator and provide the completed written exam to the Doctoral Program Committee 2 weeks before the scheduled defense. A majority of the PhD Program Committee members and at least 1 of the student's research mentors must attend the oral comprehensive defense, which is otherwise closed to the public.

Evaluation

The Doctoral Program Committee will oversee the comprehensive examinations. If necessary, subcommittees will be formed to:

- Write comprehensive examinations
- Proctor and score comprehensive examinations
- Ensure that the student satisfactorily provides all modifications and revisions requested by the committee

When a student does not pass the first comprehensive examination the student will receive a written communication from the Program Co-Directors detailing the deficiencies in performance and what must be accomplished to satisfy these concerns.

The second examination must be taken within three months of the first examination. Failure to resolve issues of concern on the second examination will result in termination from the Program. When a student who is already on probation fails the comprehensive examinations, they may or may not be given a second opportunity to pass that examination, at the discretion of the PhD Program Committee.

Outcome Options

Taking into account both the written and oral portions, the following options are available to the Comprehensive Examination Committee when a student takes the Comprehensive Examination:

- Pass with distinction
- Pass the overall exam
- Fail the overall exam
- Partial pass (see Determining Outcomes below for details)

A student who failed the Comprehensive Examination on a first attempt must petition the Program Co-Directors in writing to take the Comprehensive Examination a second time. The student should then work with the Administrator to find a date and time that is within 90 days of the date the first Comprehensive Examination was failed.

3. Doctoral Committee

Before being admitted to candidacy, each PhD student will form a dissertation committee that will consist of five University faculty members, including two members of the ICRE faculty, two members of the student's home department faculty (if they are a fellow or a faculty member), and one representative from a discipline other than the student's discipline. This final representative may be from outside the University of Pittsburgh. In accordance with University of Pittsburgh policies, the majority of the dissertation committee, including the committee chair, must be members of the Graduate Faculty.

The doctoral committee has the responsibility to advise the student during the progress of the candidate's research and has the authority to require high quality research and/or the rewriting of any portion of the dissertation. The committee conducts the final oral examination and determines whether the dissertation meets acceptable standards.

Throughout the process of preparing the dissertation and the dissertation defense, the student will be in regular contact with his or her committee chair in particular and with the other committee members for continued guidance. The dissertation committee has the responsibility to advise the student during the progress of the candidate's research and has the authority to require high quality research and/or the rewriting of any portion, or all, of the dissertation. The dissertation committee conducts the final oral examination and determines whether the dissertation meets acceptable standards.

Meetings of the doctoral candidate and his/her dissertation committee must occur at least twice annually from the time the student gains Admission to Doctoral Candidacy. During these meetings, the committee should assess the student's progress toward degree and discuss objectives for the following year and a timetable for completing degree requirements. It is the responsibility of the dean of each school to determine a mechanism for monitoring the occurrence of these annual reviews. All meetings of the dissertation committee should be documented by the Chair in a summary letter and reviewed by the members and the student following the meeting to ensure agreement of the research plan.

When a doctoral committee member leaves the University, he or she must be replaced unless the dissertation is almost complete or the member has an essential role on the committee. In the later case, the dean's approval should be obtained. When the chair of a committee leaves and cannot be conveniently replaced, a co-chair must be appointed from within the department, and the restructured committee must be approved by the department chair or director of the school's doctoral program and the dean. If the defense takes place within a few months of the chair's departure, the requirement of co-chairs is usually waived.

A retired faculty member may remain as a member or chair of a committee if he or she is spending considerable time in Pittsburgh or its vicinity and is still professionally active. Retired faculty who meet these criteria may also be appointed as a member or as a co-chair (but not chair) of a newly-formed committee. Retired faculty who leave the Pittsburgh area and/or do not remain professionally active should be replaced on committees and the revised committee must be approved by the department chair or the school's director of doctoral programs and the dean.

4. Dissertation Prospectus Meeting

Each student must prepare a dissertation proposal for presentation to his/her doctoral dissertation committee at a formal dissertation overview meeting. At this meeting, the student will present his/her research plan to the dissertation committee.

The dissertation committee members will provide guidance in shaping the conceptualization and methodology of that plan. The dissertation committee must unanimously approve the dissertation topic and research plan before the student may be admitted to candidacy for the doctoral degree.

If the research proposed in the overview or prospectus involves human subjects, the proposed research must be approved by the University Institutional Review Board (IRB) before it may be carried out.

5. Admission to Candidacy

Admission to candidacy for the PhD degree in Clinical and Translational Science constitutes a promotion of the student to the most advanced stage of graduate study and provides formal approval to devote essentially exclusive attention to the research and the writing of the dissertation.

To qualify for admission to candidacy, students must:

- Be in full graduate status
- Have satisfied the requirement of the preliminary evaluation
- Have completed formal course work with a minimum quality point average (QPA) of 3.00
- Have passed the comprehensive examination
- Have received approval of the proposed subject and plan of the dissertation from the dissertation committee following a prospectus meeting of the committee

Students will be informed of admission to candidacy by written notification from the Associate Dean for Graduate Studies of the School of Medicine, who also will state the approved dissertation committee's composition.

6. Doctoral Dissertation

Format Options

The first option is to submit three first-authored manuscripts that have been accepted for publication in peer-reviewed journals. The three manuscripts must be thematically related to one another and to the dissertation proposal that was approved by the student's five-member dissertation committee. The manuscripts must be accompanied by an introductory chapter that discusses the context in which the research was performed and by a concluding chapter that discusses the implications of the research findings and provides a description of plans for future research.

The second option is to submit a more traditional dissertation that includes, at a minimum, chapters describing the background, methods, analyses/results, and conclusions of the dissertation project.

Either option must involve a substantive piece of original and independent research grounded in an appropriate body of literature and theory. High priority – both during the process of selection of the dissertation research topic and in the evaluation of the product of the dissertation research – will

be placed on the extent to which the project is innovative and advances the field in which the student is working.

The written work must conform to the University of Pittsburgh style manual. All dissertations must be submitted electronically using Electronic Theses and Dissertations Software. Students may use a professional editor in the preparation of the dissertation, but the assistance must be limited to help with language and not with subject matter or interpretation.

Scheduling the Defense

The dissertation defense must be scheduled through the PhD Program Administrative offices at least 2 months in advance and at a time that is convenient for the student and all five committee members.

Announcement of Dissertation Defense

The date, place, and time of the examination should be published well in advance in the *University Times*. An announcement of the dissertation defense must be posted and distributed in the same way as ICRE seminar presentations (via email) and are announced at least two weeks prior to the date of the seminar.

Final Written Dissertation

The written work must conform to the University of Pittsburgh style manual. The style manual can be found at:

<http://www.pitt.edu/~graduate/etd/formatguidelineshtml.html>

Students may use a professional editor in the preparation of the dissertation, but the assistance must be limited to help with language and not with subject matter or interpretation.

The chair of the dissertation committee should ensure that the dissertation is in final form before requesting signatures of the members of the committee for final approval following the oral defense.

Final Oral Defense

The dissertation defense is an oral presentation and examination of the student's research. In the defense, the student should provide an overview of the following:

- Aims of the project
- Literature from which the project is an outgrowth
- Significance and contribution of the project to the research area; methods, analysis, and results; and implications of the research findings

The final oral examination in defense of the doctoral dissertation is conducted by the student's dissertation committee and need not be confined to materials in and related to the dissertation.

Any member of the Graduate Faculty of the University may attend and participate in the examination. Other qualified individuals may be invited by the committee to participate in the examination. Only members of the dissertation committee may be present during the final deliberations and may vote on the passing of the candidate.

A Doctoral Dissertation Report of this examination, signed by all the members of the dissertation committee, must be sent to the Associate Dean for Graduate Studies of the School of Medicine.

If the decision of the committee is not unanimous, the case is referred to the Dean for resolution.

7. Applying for Graduation

It is the student's responsibility to file the Graduation Application form with the PhD Student Services Coordinator by the publicized due dates. Students must submit the Graduate Application Form by the due date for the term in which they expect to complete all degree requirements.

Students should be aware that according to University policy they are responsible for the completion of their degree requirements. Incomplete grades (G/I) for coursework required for degree satisfaction should be completed before the week of final exams of the term in which a student intends to graduate.

H. Mentoring

1. Team Mentoring Model

Mentoring, as well as the training, monitoring, and evaluation of mentoring, is central to the PhD in CTS. The PhD program views mentoring as an essential component to successful progress towards their degree and overall career development. The collaborative nature of clinical and translational research requires a "team-based approach" for mentoring. In this model, the mentors meet with the student as a team. Students in the PhD program will be expected to assemble a multidisciplinary mentoring team within their first year.

2. Mentor Training

All new PhD students and their mentoring team will be required to participate in the ICRE Mentoring Training Program in the fall of each academic year. The goals of the training are:

- to provide a clear understanding of the purpose of mentoring
- to delineate the expectations of the trainees
- to develop consistent implementation of mentoring
- to formalize the concept of team mentoring and the nonnegotiable aspects of the mentoring contract
- to provide professional skills training (e.g. negotiation, active listening, etc)

3. Selection of Mentors

All PhD students will be advised to choose a primary and secondary mentor by the start of the Year 1. The primary mentor has to be finalized by the year of end Year 1. The program Co-Directors will assess the compatibility of the student's proposed research with their selected mentors and work

with each student once they have been accepted into the program to help them identify a mentor if one is not already selected.

Primary mentors for PhD students must be highly accomplished independent investigators who have an established track record of mentoring and funded research.

The expectation of the program is that mentoring teams will meet with the student on a regular basis to:

- design plans of study
- discuss research progress
- solve specific issues and problems arising during research
- advise on project management
- help guide data collection analysis, manuscript preparation, and other functions including the provision of completing the dissertation and career development advice

4. Mentoring Expectations and Contracts

At the beginning of the program, students and their mentors will meet to establish the expectations of their mentoring relationship. This includes:

- Set realistic goals and expectations
- Develop a schedule for regular meetings
- Develop an agenda for each meeting
- Set rules surrounding feedback
- Negotiate rules for reminders
- Clarify expectations regarding papers and authorship

These contracts allow the students and mentors to establish and document the expectations for the mentoring relationships and create educational objectives consistent with these expectations. The contracts also provide a formal mechanism for ensuring that progress is made in achieving the educational goals and will be used to provide individual feedback to the mentors and students and serve as a tool for evaluation.

5. Evaluation and Intervention Process

The Program Co-directors will monitor and evaluate the mentoring of the program by direct participation/observation in student mentoring meetings, discussions with students, and timed evaluations completed by the mentors.

I. Evaluation of Students

1. Annual Progress Reports

By June 30 of each year, all students must submit a 1-2 page progress report to the PhD Program Administrator summarizing their activities during the past year and their plans for future study. This report will serve as the focal document for the annual student evaluation by the Program Co-directors and Program Committee, although reports from the student's research mentor, committee chairpersons, course instructors, teaching supervisors, etc. will also be incorporated into the

evaluation. Therefore, the progress report should incorporate everything the student wishes the faculty to know at the time of the evaluation. It should be organized as follows:

- A statement of prior year's goals and the extent to which they have been achieved
- A list of the courses taken and the grades attained
- A description of research efforts including clearly stated scientific rationales and goals
- A list of Program "milestones" completed
- A list of any awards or honors attained
- A list of manuscripts and abstracts published
- A list of attendance and presentations at scientific conferences
- A statement of specific objectives for the coming academic year

2. Annual Evaluation

All students are evaluated by the Program Co-directors and Program Committee Program Committee each year beginning in July. Results of these evaluations are reported to each student in a letter from the Co-Directors of the Program. This letter may be supplemented by a discussion between the student and a member of the committee to clarify the letter, if necessary, or to discuss additional aspects of the student's progress. Students are also encouraged to discuss this evaluation with their research mentor.

In evaluating students, the committee considers performance in mentored research, course work, seminars, teaching (if applicable), mastery of the relevant scientific literature, performance on any major examinations that have been taken during the past year, and contributions to the community at large. Copies of the yearly evaluation letter are sent to the student's mentors and become a part of the student's file.

3. Academic Standards

Probation

The University requires that all graduate students maintain a QPA of 3.0 or above to undergo the preliminary evaluation, to take the comprehensive examination, to be admitted to candidacy for the Ph.D. degree, and to be graduated. Students whose QPA falls below 3.0 must be put on "University probation" and cannot be awarded financial assistance from the University (e.g., stipends) until they have re-established a QPA of 3.0 or above.

When a student who is not on probation fails one of the major milestones, the student will be placed on probation and given a second opportunity to pass that examination. The student will receive a written communication from the committee that evaluated performance on the exam detailing the deficiencies in performance and what must be accomplished to satisfy these concerns. The second examination must be taken within three months of the first examination. Failure to resolve issues of concern on the second examination will result in termination from the Program. When a student who is already on probation fails one of the major examinations, they may or may not be given a second opportunity to pass that examination, at the discretion of the CTS PhD Program Committee.

Termination from Program

Students may be terminated from the CTS PhD Program for:

- failure to pass any required core courses
- unsatisfactory results on the Preliminary Evaluation
- failure of the Comprehensive Exam
- failure to advance an acceptable dissertation proposal
- failure to make adequate progress in mentored research including unsatisfactory performance in the Second Year Evaluation
- breaches in ethical conduct such as plagiarism

Except for instances involving breaches in legal or ethical behavior, students will not be terminated from the Program without first being notified in writing that they have been placed on probation. This written communication will include a detailed description of the reason(s) for placing the student on probation, and the goals that the student must accomplish in order to regain good standing in the Program. Students will typically have one term to resolve their problems and get off probation, or they will be terminated from the Program.

When a student is informed that his/her research progress has been judged unsatisfactory, the student will be given one term to improve skills and productivity before being reevaluated. A second determination that research performance is substandard, at this time or during any subsequent evaluation, will result in the student's termination from the program.

In all cases, the termination of a student requires a decision by the CTS PhD Program Committee and acceptance of a recommendation for dismissal by the Co-Directors of the Program. Termination decisions cannot be made by an individual faculty member or examination committee. Terminations are final.

Terminal Masters Degree

The PhD in CTS does not accept students whose goal is to attain a MS degree. However, under certain circumstances a student may find it necessary to resign from the PhD program or may be terminated from the PhD program for academic reasons. In either of these circumstances, a student may petition to be transferred to the Clinical Research MS program. The petition must be addressed in writing to the program Co-Directors and have the support of the student's dissertation advisor. In this case, students must fulfill all of the requirements for a MS degree in Clinical Research.

Dispute Resolution

The Clinical and Translational Science PhD Program Committee may resolve disputes that arise between a student, their mentor, dissertation chair or committee member, or a course instructor. If a dispute arises between the Doctoral Program Committee and the student, a mentor, or dissertation committee member (e.g., discordant views on acceptable progress) that cannot be resolved within the committee by the involved parties, then the matter will be referred to the Associate Dean for Graduate Studies who may elect to refer the matter to the Dean.

IV. Academic Policy and Procedures

A. Statute of Limitations

It is University policy that students complete the Certificate or Master of Science degree in four (4) years. Under extraordinary circumstances, students may apply for an extension of the statute of limitations. The request must be approved by the Director, Program Leadership, and the Dean.

B. Cross Registration

Students may register for courses offered at institutions in the Pittsburgh Council on Higher Education (PCHE) cross-registration agreement (Carnegie Mellon, Duquesne University, the Pittsburgh Theological Seminary, and Robert Morris University.) Such coursework must be approved in advance by the student's advisor. Credits will not be counted as transfers and will count toward the degree and GPA calculations.

C. Waiver of Requirements

If a student feels that his or her educational background precludes the need to take one or more of the required courses, the student should discuss this with their ICRE advisor and the Course Director. The advisor will bring the matter to the attention of the ICRE Leadership for the Degree-granting Programs. In some cases, the student may receive permission to take an examination to be exempted from a course. There is a fee of \$10.00 to test out of a required course, and the student will be responsible for paying the fee.

D. Grading Policy

The following guidelines are based on University policy:

- Graduate students must maintain a minimum grade point average (GPA) of 3.0 or better at all times. Failure to do so results in automatic academic probation.
- Graduate students must receive satisfactory grades in each course. For required courses, a letter grade of "B" or better is needed. For elective courses, a letter grade of "B –" can count towards fulfillment of degree requirements, subject to approval by the Director.
- If a student receives a letter grade that falls below these thresholds ("B" for required courses, "B –" for elective courses), no course credit will be given. The University will not count these courses towards requirements of the degree program, regardless of the student's overall grade point average.

Students placed on probation must be informed of this sanction and its consequences in writing. As part of the process, the Director must decide whether to allow a student who earned a "B –" or less in a required course to re-take the course or to dismiss the student from the program.

E. Tuition

Students are responsible for covering the tuition costs, taxes, and fees associated with courses taken through the Institute for Clinical Research Education unless they have other funding sources. The Institute for Clinical Research Education does not provide financial aid. Current tuition rates for graduate-level courses at the University of Pittsburgh can be viewed at:

<http://www.ir.pitt.edu/tuition/index.html>

Additional information on tuition at the Institute for Clinical Research Education can be found at:

<http://www.icre.pitt.edu/tuition.html>

Many individuals accepted into our degree-granting programs have faculty- or student-based affiliations with the University of Pittsburgh or University of Pittsburgh Medical Center (UPMC). Faculty, fellows, or residents at these institutions may be eligible for tuition benefits. For complete information, contact the Faculty Records office at the University of Pittsburgh (412-624-4232) or UPMC Tuition Assistance Employee Service Center at 1-800-994-2752 (press option 3).

F. Leave of Absence

Under special conditions, a student in the Master of Science program may be granted one leave of absence for a maximum amount of 1 year. When requesting a leave of absence, the student must state the rationale and must indicate the requested length of leave in advance. The request should be submitted to the Director, who in turn will make a recommendation to the Associate Dean. If approved by the Associate Dean, the time of the leave shall not count against the total time allowed for the degree being sought by the student.

G. Building Emergency or Inclement Weather Policy for Students

Scenario 1: The University is closed; the School of Medicine is closed.

Scenario 2: The University cancels classes; the School of Medicine cancels classes.

- Only the Chancellor may officially close the Pittsburgh campus of the University.
- The University will remain open in all but the most extreme circumstances. However, University employees and students are urged to use their own discretion in deciding whether they can safely commute to work.
- When a State of Emergency is declared by the Governor or other local governing official, school personnel are expected to abide by those directives, and there will be no classes.

V. ICRE Program Guidelines

A. CourseWeb

Most, but not all, ICRE courses are made available on the University of Pittsburgh CourseWeb system. Available course materials include syllabi, announcements, and, for some courses, audio, audio with PowerPoint, and/or video recordings of the lectures.

1. Availability of Course Information

CourseWeb courses will be available sometime in the two week period before the start of the course, depending on availability of information. Students registered for the course will receive a welcoming email when the course is available on CourseWeb. Periodic updates to the syllabi and other information on CourseWeb will be made as needed. At course completion, the CourseWeb course will continue to be accessible for two weeks after the last day of class. This extension provides enrolled students with an opportunity to save any files made available for the course. There will be no access to the course information after that time unless an exemption is permitted by the instructor.

2. University of Pittsburgh Email

CourseWeb and all official University of Pittsburgh correspondence are directed to the student's University of Pittsburgh email address (username@pitt.edu). Students are responsible either for reading email at their University of Pittsburgh email address or for forwarding email messages to an email account that the student regularly uses. University of Pittsburgh webmail can be accessed at the Pitt Portal:

<http://my.pitt.edu>

For information on forwarding your University of Pittsburgh email, see the University Email Help page at:

<http://technology.pitt.edu/help/help-index/email-accounts-help.html>

3. Lecture PowerPoint Slides

The instructor for each course that is available on CourseWeb may opt to post a PDF of lecture PowerPoint slides before start of class. The instructor will notify the class of the course policy on posting of lecture PDFs in the first class. If the PDFs are posted before the lecture, the student is responsible for printing the notes. For those classes, the instructor will no longer distribute printed copies in class.

B. Attendance

Attendance is required of all students in degree-granting programs at ICRE. A computerized sign-in attendance system has been designed to collect attendance for all courses held in the Parkvale Building. All students must sign-in before entering the classroom at computers that can be found in the lobby area on the second and third floor of the Parkvale Building. These computers are only available when classes are in session. Students can begin to sign-in 30 minutes before the scheduled

class time and up to an hour after the class has started. Courses held in buildings other than the Parkvale Building may have a paper sign-in sheet distributed during class.

If a student is not listed on the computerized sign-in roster for a course to which they are registered, they must add their name to the roster by clicking the link to add a member to the roster found at the bottom of the sign-in page.

Watching a video of a recorded lecture does not substitute for attendance. Attendance exceptions are made at the instructor's discretion.

C. Course Evaluation

All students are expected to complete a course evaluation survey at the end of each ICRE course. Course evaluations will be distributed in the classroom at the end of the semester or will be made available as an online survey. All responses are confidential and will be presented to the instructor without any identification of the responder. If you have not completed the survey, you will receive an email reminder to do so since the student evaluations are a key component for course and program improvements.

D. Copyrighted Material Policy

1. University of Pittsburgh Copyright Policy

The formal University of Pittsburgh policy for copying copyrighted material can be found at:

<http://www.bc.pitt.edu/policies/policy/10/10-04-01.html>

Additional information on copyright can be found at:

<http://www.library.pitt.edu/guides/copyright/>

Copyrighted material

Copyrighted material is defined as:

- Literary works, such as journal articles and books
- Pictorial, graphic, and other audiovisual works
- Sound recordings
- Computer software

Almost any form of creative work may be subject to copyright protection.

Photocopying/Reproduction

When photocopying or reproducing material, only a single copy of a copyrighted article or a minor part of a work may be used for personal use. The copy of the copyrighted work becomes the property of the person who made it. It is not permissible to copy an entire issue, volume, or complete work.

Public Domain

Almost everything copyrighted in 1905 or earlier is now in the public domain and multiple copies may be made. In rare instances, a private law has been passed by Congress to provide extended copyright protection for a title. While some materials since 1906 have come into the public domain, the University and its libraries are not equipped to perform copyright searches to identify those materials that are no longer protected.

2. ICRE CourseWeb Copyright Policy

Due to changes in the copyright law, the ICRE is no longer able to post and distribute copyrighted material to students directly on CourseWeb. This complies with University of Pittsburgh Policy #10-04-01. This means that the ICRE will no longer post PDFs of required/supplemental readings on CourseWeb. Students may purchase any required or supplemental textbooks or use one of the methods listed below.

References

References to all required and supplemental reading material will be supplied via the course syllabus and/or CourseWeb.

Required and Supplemental Textbooks

Single copies of required textbooks are available in the ICRE Reference Library (Parkvale Building, Suite 300, Room 302). Copies of required sections can be made for personal use only.

Required and Supplemental Journal Articles

Students have the following options to obtain required journal articles:

- A link may be provided via CourseWeb to a free, downloadable online copy of the article.
- A reference may be used to locate the article via the Health Sciences Library System (HSLs).
- A copy of the article will be available in the ICRE Reference Library (Parkvale Building, Suite 300, Room 302).

Copies of required journal articles may be made for personal use only.

E. Library Resources

The ICRE Reference Library (Parkvale Building, Suite 300, Room 302) has a collection of required and supplemental textbooks and journal articles for ICRE courses. The books in the ICRE Reference Library are available for photocopying purposes only. The books and reading binders may not be taken from the building or borrowed overnight and must be returned in the condition in which they were initially borrowed.

Single photocopies can be made for personal use only. Multiple copies cannot be made for distribution to fellow students, friends, co-workers, or family.

All course readings and textbooks can also be found at the Health Sciences Library System (HSLs) (200 Scaife Hall).

The University Library System (ULS) and Health Sciences Library System (HSLs) are available to all students. Reference questions can be directed to a ULS Librarian by a variety of methods listed here:

<http://www.library.pitt.edu/reference/>

Reference questions can be directed to an HSLs Librarian here:

<http://www.hsls.pitt.edu/askalibrarian/>

VI. Guidelines in Academic Integrity

A. University of Pittsburgh Code of Conduct

The Code of Conduct outlines non-academic standards of conduct appropriate to the University in consonance with the educational goals of the University.

Students are expected to conduct themselves as responsible members of the University community. Those students whose conduct demonstrates a disrespect for law, the rights of others, or the health, welfare and safety of members of the University community will be subject to disciplinary action by the University, only if such conduct takes place on University property or in the course of a University-sponsored or supervised activity, if such conduct results directly from membership in the University community, or if such conduct does not fall into one of the preceding categories but poses a direct, physical threat to the University community or any individual member thereof, even if such conduct occurs off campus.

B. University of Pittsburgh Honor Code

The faculty and the students of the University of Pittsburgh School of Medicine recognize the importance of personal integrity and honor. To achieve this end, each student accepting an offer of admission will accept the obligations of the Honor Code/Code of Conduct and will expect to apply the code to all aspects of his or her professional life regardless of the level of training. Students and faculty of the School of Medicine shall be honor bound to enforce the Honor Code/Code of Conduct and to report violations of it.

The Honor Code/Code of Conduct emphasizes the individual's involvement in and responsibility for the corporate well-being of the community of the Medical School. In keeping with the latter, it is incumbent upon every member of the community to promote the climate that this code seeks to establish. This involves not only counseling with fellow members of the school concerning their actions, but also bringing the sanctions of the School's disciplinary procedures to bear upon those whose conduct is in violation of the Code.

The Honor Code is simply stated: "Every student shall be honor bound to refrain from cheating, from presenting work for evaluation which is not his or her own, from giving or obtaining unauthorized assistance during evaluation, and from falsifying data or reports. Every student shall be honor bound from lying under oath. Every student has an obligation to cooperate in the investigation or disposition of any allegation of violation of the Honor Code and to report all violations which come under his or her observation." Examples of conduct which have been regarded as being in violation of the Honor Code include but are not limited to the following:

- copying from an examination paper of another student
- allowing another to copy from one's examination paper
- reading a copy of the examination prior to the date of the examination without consent of the instructor
- collaborating with others in writing an examination
- plagiarism

- revising and resubmitting a quiz for re-grading without the instructor's knowledge and consent
- giving or receiving unpermitted aid on a take-home examination
- representing as one's own the work of another
- giving or receiving aid on an examination under circumstances in which a reasonable person should have known that such aid was prohibited by the Honor Code
- falsifying clinical data
- destroying or concealing for his or her own purpose educational materials meant for simultaneous use by others

If a student, while under pressure, commits a dishonorable act, it shall be considered a valid defense if the student reports himself or herself to an appropriate authority and conscientiously attempts to rectify the situation, before any knowledge of an investigation. The faculty has the obligation of providing an environment conducive to independent work during examination. Examinations often will not be monitored by the faculty, except in order to answer questions or give authorized aid. Students may be asked to add a pledge that "I have neither given nor received unauthorized aid prior to or during this examination, and that I will report any known violation on the part of others."

Any student, faculty member, administrative officer, or staff member of the School of Medicine may charge a student with violation of the Honor Code. This must be done in a timely manner. Such a charge may be brought to the attention of a member of the Honor Council, to the Dean, or the Associate Dean for Graduate Studies, any one of whom can provide advice and counsel as to how to proceed within the School's procedures.

VII. Guidelines for Ethical Practices in Research

The University of Pittsburgh seeks excellence in the pursuit of knowledge and requires all members of the University community, including its student body, to adhere to the highest standards of integrity in research. Detailed information regarding the Research Integrity Policy at the University of Pittsburgh can be found at:

<http://www.bc.pitt.edu/policies/policy/11/11-01-01.html>

More detailed information on the Guidelines for Ethical Practices in Research at the University of Pittsburgh Guidelines can be found at:

<http://www.pitt.edu/~provost/ethresearch.html>

VIII. ICRE Research Infrastructure Support

A. Clinical and Translational Science Institute

The CTSI serves as the integrative academic home for clinical and translational scientists across the University's six health sciences schools, Carnegie Mellon University, the University of Pittsburgh Medical Center (UPMC), which is one of the nation's largest and most financially successful academic health care systems, and the region. The CTSI's primary focus is to develop, nurture, and support a cadre of clinical and translational scientists by building on the University's existing clinical research training programs to establish a comprehensive program with activities ranging from early research exposure for high school students to advanced doctoral programs.

Students are encouraged to learn about CTSI and the resources available at:

<http://www.ctsi.pitt.edu/>

B. Design, Biostatistics, and Clinical Research Ethics Core

The DBE Core of the CTSI provides centralized services to trainees, fellows, and junior faculty who are conducting clinical and translational research, and educates them about these services.

Service requests for assistance can be made at:

<http://www.ctsi2.pitt.edu/ServiceRequest/index.aspx>

C. Center for Research on Health Care Data Center

The Center for Research on Health Care (CRHC) provides a forum for talented multidisciplinary investigators from throughout the university community to collaborate in high-quality health services research and train future investigators in methods and practices critical to the conduct of rigorous and exemplary research.

D. Office of Academic Career Development

The University of Pittsburgh OACD provides a supportive and collaborative environment, purposeful mentorship, and encouragement of diversity in leadership.

OACD hosts a variety of programs for post-docs and junior faculty. More information can be found at:

<http://www.oacd.health.pitt.edu/>

IX. University Facilities and Services

Facilities and services available to students in the School of Medicine are described on the website:

<http://www.medschool.pitt.edu/handbook/Studentservices.htm>