

MASTER OF SCIENCE IN CLINICAL RESEARCH  
CERTIFICATE IN CLINICAL RESEARCH

2022 PROGRAM HANDBOOK



IGRE

INSTITUTE FOR  
CLINICAL RESEARCH  
EDUCATION

UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE  
INSTITUTE FOR CLINICAL RESEARCH EDUCATION

# **Institute for Clinical Research Education (ICRE)**

## **Degree Programs in Clinical Research and Clinical and Translational Science**

This handbook provides information about the policies and procedures pertaining to the Clinical Research Degree 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 email so that students are notified in a timely manner.

Degree Granting Programs in Clinical Research Contact Information:

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The University does not tolerate discrimination, harassment, or retaliation on these bases and takes steps to ensure that students, employees, and third parties are not subject to a hostile environment in University programs or activities.

The University responds promptly and equitably to allegations of discrimination, harassment, and retaliation. It promptly conducts investigations and takes appropriate action, including disciplinary action, against individuals found to have violated its policies, as well as provides appropriate remedies to complainants and the campus community. The University is committed to taking prompt action to end a hostile environment if one has been created, prevent its recurrence, and remedy the effects of any hostile environment on affected members of the campus community.

For complete details on the University's Nondiscrimination, Equal Opportunity, and Affirmative Action Policy (07-01-03) and Sexual Misconduct Policy (06-05-01), please visit the [Policies, Procedures, and Practices](#) page.

*Last updated: January 6, 2022*

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## I. Introduction to the ICRE and Clinical Research Degree Programs

### A. Institute for Clinical Research

The Institute for Clinical Research Education (ICRE) is the home for the University of Pittsburgh's premier clinical and translational research training programs as well as the home for the Research Education and Career Development Core of the Clinical and Translational Science Institute (CTSI). The foundation of the ICRE's clinical research training enterprise consists of the Degree Granting Programs in Clinical Research.

- Mission:

The mission of the ICRE is to offer the highest-caliber training and education in clinical research to all levels of trainees in the Schools of the Health Sciences (SHS) and to enhance collaboration among trainees from multiple disciplines.

- Objectives

The ICRE's primary objectives are to develop, nurture, and support a cadre of clinical and translational scientists by building on the University of Pittsburgh's existing clinical research training programs to establish a comprehensive program with activities ranging from early research exposure for high school students to programs for faculty.

### B. Degree Granting Programs in Clinical Research

The MS and certificate programs in Clinical Research at the University Of Pittsburgh School Of Medicine prepare trainees to learn, design and conduct high-quality clinical and translational research.

- Objectives

- To attract highly talented individuals from a broad range of disciplines with interest in clinical and translational research and teach them the critical skills needed to become successful clinical researchers.
- To provide a rigorous core curriculum encompassing all of the major aspects necessary for the design and conduct of clinical and translational research.
- To offer specialized, methods-based foci that allow trainees to tailor coursework to meet their individual needs for clinical and translational research training.

## II. Clinical Research Degree Program Requirements

### A. Master of Science in Clinical Research

To obtain a Master of Science in Clinical Research, students must complete a minimum of 30 credit hours of coursework, including the core curriculum in clinical research, the grant-writing course, required courses for one of the specialty tracks focused on research methodologies, and requirements for a thesis or substantive research project. Depending on individual clinical responsibilities and the total number of courses taken, the Master of Science in Clinical Research generally requires 2 years or more to fulfill all of the requirements. The timing and scheduling for many of the courses in the program are designed to help students balance their multiple responsibilities. Students are able to decline enrollment for 1 semester. If a student does not enroll for two consecutive semesters, they must meet with a program staff member to discuss their degree plan. The University of Pittsburgh regulations regarding Master of Science degrees can be found [here](#).

#### 1. Course Requirements:

Students must complete the required core curriculum in Clinical Research. In addition, Master of Science students are required to complete Advanced Grant Writing Parts I and II (2-term grant writing course).

Summer Term	Fall Term	Spring Term
CLRES 2005: Computer Methods in Clinical Research (1 credit)	CLRES 2071/2072: Advanced Grant Writing Parts I and II (4 credits)	
CLRES 2010: Clinical Research Methods (3 credits)	Specialty Track & Elective Coursework	Specialty Track & Elective Coursework
CLRES 2020: Biostatistics (4 credits)		
CLRES 2040: Measurement in Clinical Research (1 credit)		

#### 2. Core Curriculum

The purpose of the core curriculum is to provide trainees with the basic set of skills that are required by clinical investigators in all fields of interest. These skills include an understanding of research design, epidemiologic methods, biostatistics, study and survey design, measurement of outcomes, and ethical and regulatory principles of research involving human subjects. There may be additional requirements, depending on the specific research training path. The core curriculum can be taken in its entirety in the summer. It is possible to split the core curriculum over two summer terms. A detailed plan of study for the Master of Science in Clinical Research can be found in [Appendix A](#).

#### 3. Responsible Conduct of Research (RCR) Requirement

Clinical Research Master of Science and Certificate students are required to attend 8, 1-hour [CTSI Responsible Conduct in Research workshops](#) or enroll in the ICRE course CLRES 2050: Ethics and Responsible Conduct of Research. At the time of graduation, students must have at least 8 hours of RCR

training through CTSI or have successfully completed CLRES 2050 in order to be eligible to graduate.

#### 4. Advanced Grant Writing

The Advanced Grant Writing course can be taken only after the core curriculum coursework is completed. The Advanced Grant Writing course focuses on research design and development during the fall and spring terms. Students are strongly discouraged from registering for CLRES 2071 until they have completed the Comprehensive Competency Review milestone.

- CLRES 2071 Advanced Grant Writing Part I (3 credits, Fall)
- CLRES 2072 Advanced Grant Writing Part II (1 credit, Spring)

#### 5. Specialty Tracks (Required)

Students must elect one of the following specialty tracks (detailed information in [Appendix A](#)):

- Clinical Trials (Track Director: Kaleab Abebe, PhD)
- Comparative Effectiveness (Track Director: Holly Thomas, MD, MS)
- Data Science (Track Director: (Joyce) Chung-Chou H. Chang, PhD)
- Health Services Research (Track Director: Kenneth Smith, MD, MS)
- Implementation Science (Track Director: Charles Jonassaint, PhD, MHS)
- Innovation (Track Director: Mary Goldberg, PhD)
- Translational Research (Track Director: Patrick J. Pagano, PhD, FAHA)

#### 6. Comprehensive Competency Review

After completion of 15 credits inclusive of the core (CLRES 2005, CLRES 2010, CLRES 2020, and CLRES 2040) and before registering for any thesis credits, students will meet with their Specialty Track Director, and Dr. Colleen Mayowski for a Comprehensive Competency Review ([Appendix B](#)).

#### 7. Thesis or Substantive Research Project

Individuals pursuing the Master of Science in Clinical Research are required to complete a formal thesis or substantive research project. The project will count for up to 3 credits and must satisfy the following requirements

- Be primarily independent work by the trainee, receive preliminary approval from both the trainee's advisor and the ICRE Leadership,
- Form the basis for a comprehensive review of competence by a formal review committee

There are three standard mechanisms that are considered appropriate for the substantive research project (see below), subject to ICRE approval. To obtain approval, the trainee must complete a Prospectus and Review Committee Form the last day of the term PRIOR to the term you wish to register for CLRES 2080: Masters Thesis Research credits. The prospectus must be approved by the student's advisor and the Director of Academic Programs before the student may proceed. The Prospectus forms are provided to students at the beginning of each term via email or by contacting the ICRE Degree Program Staff.

The mechanisms for the substantive project include:

- *A standard thesis option:* trainees may elect to complete a master's thesis in their field of specialty. A thesis produced under this option must conform to all applicable university policies regarding theses (visit [www.pitt.edu/~graduate/etd](http://www.pitt.edu/~graduate/etd) for details on submitting theses electronically).
- *R01, K-award, or equivalent grant application:* Eligible students may submit a completed R01 or equivalent research proposal (for which they are the principal investigator) as evidence of their ability to plan and conduct independent research. To serve as the substantive project for the Master of Science in Clinical Research, the proposal must be reviewed and approved by the appropriate scientific review committee in the trainee's department.
- *Peer review publications:* The compilation of two completed first author papers related to the trainee's research may be used as evidence of independent work at the discretion of the individual specialty track. The papers must be original research papers and be written in a competitive manner. Each paper must be reviewed by at least 2 committee members who are not coauthors. At least one member of the committee must be independent (i.e., not a coauthor on either paper), and no committee member (except the trainee's mentor) can be a coauthor on both papers.

Each of the options listed above must be reviewed and defended before a review committee, and members of the committee must be identified when the trainee submits the prospectus and review committee form for approval. The ICRE Review Committee is chaired by your ICRE academic advisor (or another ICRE faculty member named by the advisor). The Committee also must include your mentor, another ICRE faculty member, and at least one ad hoc member familiar with your project. The Committee Chair will determine if an additional reviewer with statistical or other methodological expertise is necessary.

The trainee's presentation to the review committee should be scheduled **at least two months prior to graduation** to allow enough time for revisions and subsequent reviews. Once approval is granted by the review committee and formal documentation is submitted to the ICRE, the trainee will receive a passing grade and will be permitted to proceed with the graduation ceremonies.

Our goal is to avoid any undue expectations for students and to ensure that degree candidates across all of our programs are treated fairly and equitably. As part of this effort, students are not permitted to provide food and/or beverages to their committee for the thesis/dissertation defense or during any other milestone meetings.

## **B. Certificate in Clinical Research**

To obtain a Certificate in Clinical Research, students must complete a minimum of 15 credit hours of coursework, including the core curriculum in clinical research and 5 elective credits. Depending on individual clinical responsibilities and the total number of courses taken, the Certificate in Clinical Research generally requires 1 - 2 years of study to fulfill all the requirements; students have up to 4 years though to complete. The timing and scheduling for many of the courses in the program are designed to help students balance their multiple responsibilities. Students are able to decline enrollment for 1 semester. If a student does not enroll for two consecutive semesters, they must meet with a program staff member to discuss their degree plan. In addition to the regular Certificate in



Clinical Research, there is also the Certificate in Clinical and Translational Science for Doctoral Students in the Health Sciences (CTS Certificate). This certificate is for other PhD students in any of the Schools of Health Sciences and is completed in conjunction with their doctoral degree.

### 1. Course Requirements

Students must complete the required core curriculum in Clinical Research. In addition, they are required to take 6 credits of elective coursework. A Plan of Study can be found in [Appendix C](#).

Summer Term	Fall Term	Spring Term
CLRES 2005: Computer Methods in Clinical Research (1 credit) CLRES 2010: Clinical Research Methods (3 credits) CLRES 2020: Biostatistics (4 credits) CLRES 2040: Measurement in Clinical Research (1 credit)	Elective Credits	Elective Credits

### 2. Core Curriculum

The purpose of the core curriculum is to provide trainees with the basic set of skills that are required by clinical investigators in all fields of interest. These skills include an understanding of research design, epidemiologic methods, biostatistics, study and survey design, measurement of outcomes, and ethical and regulatory principles of research involving human subjects. The core curriculum can be taken in its entirety in the summer. It is possible to split the core curriculum coursework over two summer terms.

### 3. Responsible Conduct of Research (RCR) Requirement

Clinical Research Certificate students are required to attend 8, 1-hour Responsible Conduct in Research workshops. These workshops are offering through the Clinical and Translational Science Institute (CTSI). More information and a schedule of these workshops can be found [here](#). The ICRE will work with CTSI to track student attendance. At the time of graduation, students must have at least 8 hours of RCR training in order to be eligible to graduate.

## III. General Academic Program Information

### 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. 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.

### **C. 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. PCHE cross-registration is only available to full-time students and is limited to one class per semester. Credits will not be counted as transfers and will count toward the degree and GPA calculations. Part-time students interested in enrolling at another Pittsburgh institution may be eligible to enroll as a non-degree student at the institution and transfer the credits to their Pitt program once they successfully complete the course. (see "Waiver of Requirements" section below).

### **D. Waiver of Requirements/Transfer Credits**

If a student feels that their 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 Director of Academic Programs. The student is responsible to bring this matter to the attention of the Director of Academic Programs and will need to have the syllabi from the courses they feel meet the requirements. The Director of Academic Program is responsible for granting the waiver and in special circumstances may request the advice of the course director. Master of Science students can request up to 6-credits of previously completed, relevant coursework to be transferred into their degree. Certificate students can request up to 5-credits for transfer. In order to be eligible to transfer, the previously completed courses must be graduate-level and must be accompanied by an official transcript showing a letter grade of "B" or better (or equivalent according to the grading scheme of the institution.) Credit transfer requests must be approved by the Program Director as well as the Associate Dean of Graduate Studies in the School of Medicine. Credit transfer requests are prepared and submitted by the Assistant Director of Academic Programs. In some cases, the student may receive permission to take an examination to be exempted from a course.

### **Prior Completion of the Research Education in Advancing Investigative Careers for Housestaff and Fellows (REACH) Program**

Up to 6 credits will be accepted for the Master of Science in Clinical Research for students who have earned a letter grade B or better in the REACH program and have been accepted into the Master's degree program. Rather than retake material that has already been covered, such students will make up the 3-credit differential with additional electives. (3 credits are the difference between the 9-credit summer core and the 6 credits that can be granted to former REACH trainees).

### **E. 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 of Academic Programs.
- 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. The student has the option to re-take these courses. Students must officially enroll and pay for the class again. A repeated course, has a notation appearing underneath the previous course taken designating it has been excluded from the GPA. The course and grade remains on your record/transcript.
- An “I” grade is issued by the instructor. It is issued in the case of ongoing study such as incomplete research, work in individual guidance classes, clinical work or seminars. “I” grades are also issued when extenuating circumstances prevent a student from completing a course.
- “W” Grade: To withdraw from a class after the official end of the add/drop period while still enrolled in other courses, you must process a Monitored Withdrawal Request form through the dean's office of the academic center offering the course. If approved, a grade of “W” will be recorded on your transcript for that course. “W” grades do not count toward a student's degree or grade point average. There is no tuition adjustment associated with a course withdrawal.

## F. 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 [here](#).

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).

## G. Building Emergency or Inclement Weather Policy

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

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

Scenario 3: The Parkvale Building is closed or instructor must cancel class due to extenuating circumstances.

- 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.
- ICRE Degree Program staff will contact students as soon as possible if the Parkvale Building or instructor cancels class. It is up to the instructor to decide if a make-up session for the missed class will be scheduled and/or required.

#### IV. ICRE Academic Values and Code of Professionalism

The University of Pittsburgh and the Institute for Clinical Research Education (ICRE) maintain an honor code for all students enrolled in educational programs. The ICRE expects all students to uphold the following values for academic integrity and Code of Professionalism. Please note that specific academic integrity policies may vary from instructor to instructor; it is up to the student to understand and follow each instructor's policy and expectations.

*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 any circumstances. 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.*

Students sign and return the ICRE Academic Integrity Pledge at Orientation ([Appendix D](#)) and if found in violation of the ICRE Academic Integrity Policy will follow the steps outlined in the ICRE Academic Integrity Violation Reporting Procedure ([Appendix E](#)). In addition to these documents, students may refer to our Student Obligations ([Appendix F](#)) and Instructor Obligations ([Appendix G](#)).

##### A. Academic Integrity\*

Examples of conduct which have been regarded as being in violation of academic integrity include but are not limited to the following:

- Plagiarism
- Representing the work of another as one's own
- Destroying or concealing educational materials meant for simultaneous use by others
- 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
- 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
- Using unauthorized resources in the completion of an examination

If a student, 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 the dishonorable act is brought to the attention of the program. Any student, faculty member,

administrative officer, or staff member of the ICRE may allege that a violation of academic integrity has occurred. Alleged violations should be brought to the attention of the Director of Academic Programs immediately. The Director of Academic Programs will review the alleged violation and follow the ICRE's academic integrity violation reporting procedure. A written copy of the procedure may be obtained from the Degree Program Coordinator at any time.

## **B. Code of Professionalism\***

### **Honesty**

In all situations, classroom, lab, and office, the student should be honest with, faculty members, and other students. Cheating, plagiarism, theft, and lying are all forms of dishonest behavior.

### **Fairness**

Classroom and research expectations should be clearly stated and met. The student has the right to expect fairness in treatment, just as the teaching faculty expects to receive fair treatment. Unfair behavior is not acceptable just because someone else displays such behavior.

### **Respect**

Show respect for your teaching faculty and fellow students by attending each class, showing up on time, and staying for the entire class. Pay attention to the discussion and contribute meaningful responses.

### **Responsibility**

Take responsibility for your actions. Discourage dishonest behaviors and dishonest activities in others.

### **Communication**

Inform instructors or degree program staff in a timely manner when experiencing any issues that may impact your studies.

\* Adapted from the University of Pittsburgh School of Medicine 'Student Code of Professionalism' and the School of Medicine Program in Integrative Molecular Biology (PIMB) Student Handbook

## **V. 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 [here](#).

More detailed information on the Guidelines for Ethical Practices in Research at the University of Pittsburgh Guidelines can be found [here](#).

## **VI. ICRE Program Guidelines**

### **A. 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. Students can begin to sign-in 30 minutes before the scheduled class time up to the end of class. If you experience trouble with the sign-in, you should contact your course instructor to ensure you are given credit for attending class. 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.

## **B. Course Registration and Academic Advising**

Students are required to meet with their academic advisor (assigned to them at Orientation) each term. Students are expected to come prepared when meeting with their advisor, students should take with them a blank enrollment form, a list of proposed classes and be prepared to discuss their degree progression. Students cannot register for classes unless they have a signed enrollment form.

## **C. 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.

CourseWeb courses will be available sometime in the two week period before the start of the course, depending on availability of information. At course completion, the CourseWeb site 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.

## **D. 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. For information on forwarding your University of Pittsburgh email, see the University Email Help page [here](#).

## **E. Course Evaluation**

All students are expected to complete a course evaluation survey at the end of each ICRE course. Course evaluations are distributed electronically on the last day of class and available for two weeks. All responses are confidential and will be presented to the instructor without any identification of the responder.

## F. Required and Supplemental Textbooks

All required and supplemental textbooks can be purchased at the [University of Pittsburgh Book Center](#). The ICRE Reference Library (Parkvale Building, Suite 300, Room 311) has a collection of required and supplemental textbooks for ICRE courses. The books in the ICRE Reference Library are available for students to read in the Parkvale building only.

## VII. Program Governance

### A. Degree Granting Programs in Clinical Research

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### B. Institute for Clinical Research Education

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Director

Wishwa N. Kapoor, MD, MPH  
Founder and Director of Strategic Planning

Megan Miller, MEd  
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## **VIII. Appendices**

Appendix A: Master of Science in Clinical Research Plan of Study

Appendix B: Comprehensive Competency Review

Appendix C: Certificate in Clinical Research Plan of Study

Appendix D: ICRE Academic Integrity Pledge

Appendix E: ICRE Academic Integrity Violation Form

Appendix F: Student Obligations

Appendix G: Faculty Obligations

## Appendix A: Master of Science in Clinical Research Plan of Study

Trainees must successfully complete the required courses plus additional elective courses, selected with the trainee's advisor, which are necessary to earn the Master of Science in Clinical Research Education. The Master of Science trainee must select a track. Once the track has been selected, the trainee must take the required courses for that track. The trainee may select courses from the suggested track elective list or electives of their choosing.

### Required Core plus Advanced Grant Writing Courses

Course Number	Course Title	Required/ Elective	Credits
CLRES 2005	Computer Methods in Clinical Research	Required	1
CLRES 2010	Clinical Research Methods	Required	3
CLRES 2020	Biostatistics: Statistical Approaches in Clinical Research	Required	4
CLRES 2040	Measurement in Clinical Research	Required	1
CLRES 2071	Advanced Grant Writing Part I	Required	3
CLRES 2072	Advanced Grant Writing Part II	Required	1
	Total Credits		13

### Clinical Trials Research Track

The Clinical Trials Research Track provides training related to the design, performance, and analysis of clinical studies and relevant principles of pharmacology. Trainees are encouraged to develop a protocol for a study involving human subjects and then to direct the study and analyze the results.

<b>Course Number</b>	<b>Course Title</b>	<b>Required/ Elective</b>	<b>Credits</b>
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2021*	Analysis of Variance (ANOVA) and Regression	Required	1
CLRES 2022*	Logistic Regression	Required	1
CLRES 2120	Cost-Effectiveness Analysis in Health Care	Required	1
CLRES 2800	Fundamentals in Clinical Trials	Required	1
CLRES 2810	Statistical Methods & Issues in Clinical Trials	Required	1
CLRES 2820	Special Topics in Clinical Trials	Required	1
	Total Credits		9

- These courses are not required for students who matriculated into the MS program prior to 7/1/2020.

## Comparative Effectiveness Research Track

The CER Track addresses the emerging need for training in key disciplines within CER, including meta-analysis and systematic review, analysis of electronic records, and decision modeling and cost-effectiveness, as well as development of fundamental skills specific to clinical trials and statistical analysis of observational data. Required courses include each of these fundamental aspects, with electives to form a specialization. A final overview course will lead trainees through the development of a CER project and will tie together fundamental principles of CER.

<b>Course Number</b>	<b>Course Title</b>	<b>Required/ Elective</b>	<b>Credits</b>
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2107	Comparative Effectiveness Research	Required	2
CLRES 2108	Electronic Health Records and Developing Patient Registries	Required	1
CLRES 2120	Cost-Effectiveness Analysis	Required	1
CLRES 2121	Clinical Decision Analysis	Required	1
CLRES 2300	Introduction to Systematic Review and Meta-Analysis	Required	1
CLRES 2800	Fundamentals of Clinical Trials	Required	1
	Total Credits		10

## Health Services Research Track

The Health Services Research Track uses components of the training program developed under the Agency for Health Care Policy and Research (AHCPR) Innovation Award and the fellowship program in the Division of General Internal Medicine to offer courses in health services research methodology.

<b>Course Number</b>	<b>Course Title</b>	<b>Required/ Elective</b>	<b>Credits</b>
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2021	Analysis of Variance (ANOVA) and Regression	Required	1
CLRES 2022	Logistic Regression	Required	1
CLRES 2023	Survival Analysis	Required	1
CLRES 2026	Analysis of Correlated Data	Required	1
CLRES 2107	Comparative Effectiveness Research	Required	2
CLRES 2120	Cost-Effectiveness Analysis in Health Care	Required	1
	Total Credits		10

## Innovation Track

The innovation Track provides training in the development of new methods, ideas, or products, with the intent of translating innovation to market via licensing or generating a company

Course Number	Course Title	Required/ Elective	Credits
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2730	From Benchtop to Bedside: What Every Scientist Need to Know	Required	3
CLRES 2729	Idea to Impact	Required	1
CLRES 2085	Externship/Independent Study	Required	1
From list (below)	Additional research methods and/or statistics course(s)*	Required	2
From list (below)	Product development course**	Required	3
	Total Credits		13

\*Students choose one or two of the classes below, or other advisor approved course. Unless otherwise noted, the listed course is 1 credit:

CLRES 2021: Analysis of Variance (ANOVA) and Regression

CLRES 2022: Logistic Regression

CLRES 2023: Survival Analysis

CLRES 2025: Design and Analysis of Biomarker Studies

CLRES 2026: Analysis of Correlated Data

CLRES 2045: Survey Design and Analysis

CLRES 2107: Comparative Effectiveness Research (2 credits)

CLRES 2120: Cost-Effectiveness Analysis in Health Care

CLRES 2122: Computer Methods in Decision and Cost-Effectiveness Analysis

CLRES 2300: Introduction to Systematic Reviews and Meta-Analyses

CLRES 2400: Qualitative Research Methods

CLRES 2430: Introduction to Community Based Participatory Research

CLRES 2432: Concept Mapping: A Participatory Research Method

CLRES 2610: Research Methods in Palliative Care

CLRES 2700: Fundamentals of Bench Research (2 credits)

CLRES 2800: Fundamentals of Clinical Trials

CLRES 2810: Statistical Methods and Issues in Clinical Trials

CLRES 2820: Special Topics in Clinical Trials

\*\*Students choose one (or two in the event of a course series) of the classes below, or other advisor approved course:

BIOENG 2151/CLRES 2156: Medical Product Development (3 credits)

BIOENG 2165: Medical Product Entrepreneurship (3 credits)

HRS 2706/2718: Rehabilitation Engineering Design (2 courses, so 2nd is elective: 4 credits; 3 credits)

ENGR 2051: Product Realization (3 credits)

PHARM 5812/5825: Healthcare Innovations I & II (1 credit; 2 credits)

PHARM 5915: Executive Healthcare Innovations (1.5 credits)

### Translational Research Track

The Translational Research Track is appropriate for trainees interested in how discoveries and findings from basic research can be turned into studies of human subjects. Discoveries in basic sciences, especially the sequencing of the human genome and microbiologic advances, offer extensive opportunities for applications related to new and improved strategies for the prevention, diagnosis, and treatment of diseases.

Course Number	Course Title	Required/ Elective	Credits
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2021	Analysis of Variance (ANOVA) and Regression	Required	1
CLRES 2022	Logistic Regression	Required	1
CLRES 2700	Fundamentals of Bench Research	Required	2
CLRES 2725	Translational Research Practicum	Required	1-2
	Total Credits		8

## Implementation Science Track

The Implementation Science Track provides training in the theory, methods, and strategies necessary to be able to design interventions that ensure that evidence-based treatments may be effectively implemented in real-life settings, considering the context of the health system and local community. Trainees are encouraged to develop a funding application and/or protocol for an implementation science focused study.

Course Number	Course Title	Required/ Elective	Credits
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2021	Analysis of Variance and Regression	Required	1
CLRES 2022	Logistic Regression	Required	1
CLRES 2215	Foundations of Implementation Science I	Required	1
CLRES 2216	Foundations of Implementation Science II	Required	1
CLRES 2729	Idea 2 Impact	Required	1
CLRES 2220	Applying Quality Improvement Methods in the Clinical Context	Required	1
CLRES TBD	Implementation Science for Health Systems: Organizational Behavior Change	Required	1
CLRES 2400	Qualitative Research Methods I	Required	1
Recommended Electives	CLRES 2800 Fundamentals of Clinical Trials CLRES 2107 Comparative Effectiveness Research CLRES 2430 Intro. to Community Based Participatory Research CLRES 2431 Translating Research for Policy and Practice CLRES 2432 Concept Mapping: A Participatory Research Method CLRES 2731 From Benchtop to Bedside	Electives	



## Data Science Track

Using data science to discover and forecast insightful patterns from big biomedical data is at the core of modern medical research in managing patients' health conditions, establishing novel treatment options, and building analytical intelligence. The courses offered by the ICRE Data Science Track are designed to build essential skills in data science for clinical research that include but not limited to managing, analyzing, visualizing, and extracting meaningful information from very large healthcare data. At the end of the courses, trainees will develop fundamental knowledge and expertise in machine learning, causal inference, Bayesian statistics, and tools necessary to advancing research in precision medicine and clinical decision making.

Course Number	Course Title	Required/ Elective	Credits
CLRES 2080	Master's Thesis Research	Required	1-3
CLRES 2021	Analysis of Variance (ANOVA) and Regression	Required	1
CLRES 2022	Logistic Regression	Required	1
CLRES 2035	Fundamentals of Machine Learning in Clinical Research	Required	1
CLRES 2036	Introduction to Casual Inference	Required	1
Track Selectives (choose 1 of 4 courses listed below)			
CLRES 2108	Patient Registries and Electronic Health Records in CER	Choose 1 in this category	1
CLRES XXXX	Introduction to R programming <i>(this course is in development and will not be available until after Summer 2023)</i>	Choose 1 in this category	1
CLRES XXXX	Introduction to Bayesian Analysis <i>(this course is in development and will not be available until after Spring 2023)</i>	Choose 1 in this category	1
CLRES XXXX	Fundamentals of Machine Learning in Clinical Research – Computation <i>(this course is in development and will not be available until after Spring 2023)</i>	Choose 1 in this category	1
	Total Credits		8

## Appendix B: Comprehensive Competency Review

The MS in clinical research is intended to train you in the skills, knowledge, and professional norms appropriate for clinical researchers, with a specialization in one of six tracks. To help students be confident that they are on track to develop competence in all the key areas, the Comprehensive Competency Review (CCR) meeting takes place at the midpoint of the degree.

### Timing:

Students who plan to complete the master's degree in 2 years schedule their CCR meeting after they complete the summer core and the fall semester, usually prior to completing class registration for the following academic year. Students who plan to take less than, or more than, 2 years to earn their degree should schedule their meeting around the time they complete 15 credits.

### Process:

1. Students provide written answers to 3 questions (see Appendix C.i) that ask students to **reflect** on their learning in the program thus far. These answers should be no more 250 words.
2. Students provide evidence that they **have acquired or are on their way to acquiring** each of 6 competencies emphasized in the summer core courses: Problem formulation, methodology, sampling, measurement, data management and biomedical informatics, and applied analytic techniques.
3. From the remaining five competencies, students provide a short written reflection about **3 other competencies of their choosing**.

### Writing and submitting your CCR Document

You will be prompted to begin working on your CCR by the Program staff. You will submit your CCR as a single document as an assignment through Canvas by the date and time specified. After submission, your CCR is reviewed by your advisor and Dr. Colleen Mayowski. Following the submission and review of your CCR, your academic advisor may reach out to discuss your submission and/or request to meet.

### Unsatisfactory Review

Students who do not pass the CCR will develop, with their track director, an appropriate course of action to ensure that they are on course to become competent by graduation. Students will be offered the chance to create a new set of evidence and write new reflections of their learning within six months of the original meeting. Students will not be able to register for any thesis credits until they have passed the CCR. **Students will be strongly discouraged from taking CLRES 2071/2072 until they have passed the CCR.**

## Appendix B. i: Written Reflections

These questions are intended to make you think about your learning in the MS program thus far. Include in your answers any thoughts or comments that you think are relevant to your progress and overall

development as a clinical researcher. A template that includes an example of how some of your colleagues have answered these reflective questions is available on the ICRE Student Center on CourseWeb. (Used with permission.)

1. What is the most important skill (not knowledge) that you have acquired in the program?

*Describe why the skill is important to your career as a clinical researcher, and what has contributed to your learning in this area.*

2. Where do you feel you need to focus your learning to achieve broad competence as a clinical researcher?

*Describe why you need this skill set or knowledge, how you will acquire it, and how you became aware that you are not yet competent in this area.*

3. What have been the greatest challenges to you in the program so far?

*Consider specific areas of knowledge, skill sets, or experiences that have caused you difficulty. Describe the steps you will take to overcome these challenges in the second half of your program.*

## **Appendix B.ii: Evidence of Competence**

Select one piece of evidence that you **have acquired or are on your way to acquiring** each of 6 competencies emphasized in the summer core courses: Problem formulation, methodology, sampling, measurement, data management and biomedical informatics, and applied analytic techniques. Then, **write a short reflective statement about each artifact (piece of evidence) and why you chose it to reflect your competence.** A template that includes an example of evidence and how some of your colleagues have answered these reflective questions is available on the ICRE Student Center on CourseWeb. (Used with permission.)

Each piece of evidence should be no more than 1 page, so it could be part of a longer paper, a section from homework, a slide from a talk, etc. In selecting your evidence and thinking about the competencies, consider the following points and be prepared to answer any of these questions with your CCR committee:

- What have you learned?
- Why is this learning important?
- Why did you choose these particular pieces of evidence?
- What work did you consider as evidence and then not include? Why?
- What is there still left to work on within this competency? How will you do that?
- What is your strength in this competency that these pieces demonstrate?
- What about this competency has been difficult to acquire?
- Why do you think this competency and what you have demonstrated is important for clinical research?
- How will you apply the competency you have demonstrated in your professional life?

- How do you feel about deepening your mastery of this competency?
- How have your different learning experiences (writing, discussions, critiques, reading) come together as an integrated whole, and how will that integration deepen as you apply this competency?

Next, from the 5 remaining competencies, choose **3 other competencies that you feel you have not yet acquired** and write a short reflection about the importance of this competency and your action plan for acquiring it. The written reflection **must include an action plan for acquiring these 3 competencies**. A template that illustrates how some of your colleagues have answered these questions is available on the ICRE Student Center on CourseWeb. (Used with permission.)

### Appendix 3: CCR Form

Student: \_\_\_\_\_ Date: \_\_\_\_\_

Track Director: \_\_\_\_\_

Other Committee member: \_\_\_\_\_

	<b>Provide Evidence of Competence; 1-6</b>	<b>Does Not Meet Expectations</b>	<b>Meets Expectations</b>	<b>Exceeds Expectations</b>
1.	Problem Formulation			
2.	Methodology			
3.	Sampling			
4.	Measurement			
5.	Data Management and Biomedical Informatics			
6.	Applied Analytical Techniques			
	<b>Choose 3; Provide Action Plan</b>			
7.	Oral Communication			
8.	Written Communication			
9.	Ethics and Professional Norms			
10.	Multidisciplinary Teamwork			
11.	Management			

Specific Action Plan(s) to develop further competence:

Courses to be taken:

Topic of Thesis:

CCR Meeting outcome: Pass  Fail  (Month for next CCR Meeting: \_\_\_\_\_)

Track Director's signature \_\_\_\_\_ Student's signature \_\_\_\_\_

Committee member's signature \_\_\_\_\_

Mentor's Signature (optional) \_\_\_\_\_

## Appendix C: Certificate in Clinical Research Plan of Study

Trainees must successfully complete 15-credits as a minimum requirement for the Certificate in Clinical Research. Nine of the 15 credits will be completed within the core curriculum courses and 6 credits of elective courses, which are approved by the student's advisor.

<b>Course Number</b>	<b>Course Title</b>	<b>Required/Elective</b>	<b>Credits</b>
CLRES 2005	Computer Methods in Clinical Research	Required	1
CLRES 2010	Clinical Research Methods	Required	3
CLRES 2020	Biostatistics: Statistical Approaches in Clinical Research	Required	4
CLRES 2040	Measurement in Clinical Research	Required	1
Electives	Electives	Elective	6
	Total Credits		15

## Appendix D: ICRE Academic Integrity Pledge

### ICRE Academic Integrity and Code of Professionalism Pledge

#### Student Obligations:

1. Students should recognize their responsibility to uphold the ICRE Honor Code and Code of Professionalism (provided to you at Orientation, and included the student handbook available to all students online) and the academic policies for each course presented on the first day of class. If a student does not understand or disagrees with any of these policies, it is their responsibility to meet with the course instructor and, if needed, ICRE Director of Academic Programs.
2. Each student is required to sign the ICRE Academic Integrity and Code of Professionalism Pledge at Orientation. If a student does not sign and return the form he/she will be unable to receive a grade for their courses and will be considered in violation of the ICRE's Academic Integrity policy.

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I ( \_\_\_\_\_ ), understand the ICRE's Honor Code, Code of Professionalism. I understand that at any time I may request copies of the ICRE's Academic Integrity policies and procedures. By signing my name, I agree that I will uphold these policies and promote the integrity of the ICRE and the University of Pittsburgh.

Student Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix E: ICRE Academic Integrity Violation Reporting Procedure

1. Provide written notification to student that you suspect he/she has violated the academic integrity code and that an instructor-student meeting needs to be held.
2. You and the Director of Academic Programs will meet with the student and discuss the suspected violation. During this meeting the instructor will inform the student of the reasons he/she suspects a violation has occurred (please note that the instructor is under no obligation at this time to reveal the identities of any third party individuals who may have reported the allegation or provided any information about the allegation).
3. Following the instructor-student meeting, one option will be pursued:
  - a. If the instructor and Director believe the allegation is not supported by facts and after discussion with the student believes there was no violation, it will be dismissed and the student will be notified at the end of the meeting. Documentation of the meeting will be added to the students' official file.
  - b. If the instructor and Director still believes that an offense has occurred, they should:
    - i. Contact the ICRE Academic Integrity Committee and provide all facts pertaining to the allegation. Notify the Committee of the proposed sanctions for the accused student.
    - ii. The Committee will discuss the case and one option will be pursued:
      1. The Committee agrees that a violation has occurred and supports the proposed sanctions.
      2. The Committee do not believe a violation has occurred or do not agree with the proposed sanctions. The Committee will convene a meeting with the instructor and Director.
    - iii. Schedule a follow-up meeting with the student. During this meeting, the instructor will indicate to the student the sanction for the violation.
      1. If the student agrees with the conclusion and sanction, the instructor and student will complete an 'Academic Integrity Violation Report' form. This form will be added to their student file.
      2. If the student disagrees with the conclusion and/or sanction, the instructor will schedule a meeting with the ICRE Academic Integrity Committee, the student, and the instructor. At the request of the student, the ICRE will ensure that there is representation of the students' peers on any hearing board/committee that we would oversee if an informal/local solution cannot be found between professor-student-program director. A copy of the 'Academic Integrity Violation Report' and any background on the case will be given the Committee prior to the meeting for review. If the student disagrees with the finding after meeting, the case will then be sent to the School of Medicine Graduate Studies Office and will follow their course of action.
4. If an accused student fails to respond to the instructor to schedule a meeting in a reasonable period of time, the student will receive a finding of 'responsible for violation of academic integrity' and the instructor will apply their sanctions/punishment and inform the student of actions taken.



## Appendix F: Student Obligations

A student has an obligation to exhibit honesty and to respect the ethical standards of the profession in carrying out his or her academic assignments. Without limiting the application of this principle, a student may be found to have violated this obligation if he or she:

1. Refers during an academic evaluation to materials or sources, or employs devices, not authorized by the faculty member.
2. Provides assistance during an academic evaluation to another person in a manner not authorized by the faculty member.
3. Receives assistance during an academic evaluation from another person in a manner not authorized by the faculty member.
4. Engages in unauthorized possession, buying, selling, obtaining, or use of any materials intended to be used as an instrument of academic evaluation in advance of its administration.
5. Acts as a substitute for another person in any academic evaluation process.
6. Utilizes a substitute in any academic evaluation proceeding.
7. Practices any form of deceit in an academic evaluation proceeding.
8. Depends on the aid of others in a manner expressly prohibited by the faculty member, in the research, preparation, creation, writing, performing, or publication of work to be submitted for academic credit or evaluation.
9. Provides aid to another person, knowing such aid is expressly prohibited by the instructor, in the research, preparation, creation, writing, performing, or publication of work to be submitted for academic credit or evaluation.
10. Presents as one's own, for academic evaluation, the ideas, representations, or words of another person or persons without customary and proper acknowledgment of sources.
11. Submits the work of another person in a manner which represents the work to be one's own.
12. Knowingly permits one's work to be submitted by another person without the faculty member's authorization.
13. Attempts to influence or change one's academic evaluation, grade, or record for reasons other than achievement or merit.
14. Engages, during a class (or examination) session in which one is a student, in conduct which is so disruptive as to infringe upon the rights of the faculty member or fellow students.
15. Fails to cooperate, if called upon, in the investigation or disposition of any allegation of dishonesty pertaining to another student.

\* Adapted from the University of Pittsburgh's Suggested [Code of Conduct](#).

## Appendix G: Faculty Obligations

A faculty member accepts an obligation, in relation to his or her students, to discharge his or her duties in a fair and conscientious manner in accordance with the ethical standards generally recognized within the academic community (as well as those of the profession).

Without limiting the application of the above principle, members of the faculty are also expected (except in cases of illness or other compelling circumstance) to conduct themselves in a professional manner, including the following:

1. To meet their classes when scheduled.
2. To be available at reasonable times for appointments with students, and to keep such appointments.
3. To make appropriate preparation for classes and other meetings.
4. To base all academic evaluations upon good-faith professional judgment.
5. To describe to students, within the period in which a student may add and drop a course, the general content and objectives of a course, and the methods and standards of evaluation and grading.
6. Not to consider, in academic evaluation, such factors as race, color, religion, sex, sexual orientation, age, national origin, and political or cultural affiliation, and life style, activities, or behavior outside the classroom unrelated to academic achievement.
7. To respect the confidentiality of information regarding a student contained in University records; and to refrain from releasing such information, except in connection with intra-University business, or with student consent, or as may be permitted by law.
8. Not to exploit his or her professional relationship with students for personal advantage; and to refrain from soliciting the assistance of students for personal purposes in a manner which infringes upon such students' freedom of choice.
9. To give appropriate recognition to contributions made by students to research, publication, service, or other activities.
10. To refrain from any activity which involves risk to the health and safety of a student, except with the student's informed consent, and, where applicable, in accordance with the University policy relating to the use of human subjects in experimentation.
11. To respect the dignity of students individually and collectively in the classroom and other academic contexts.

\* Adapted from the University of Pittsburgh's [Faculty Handbook](#).