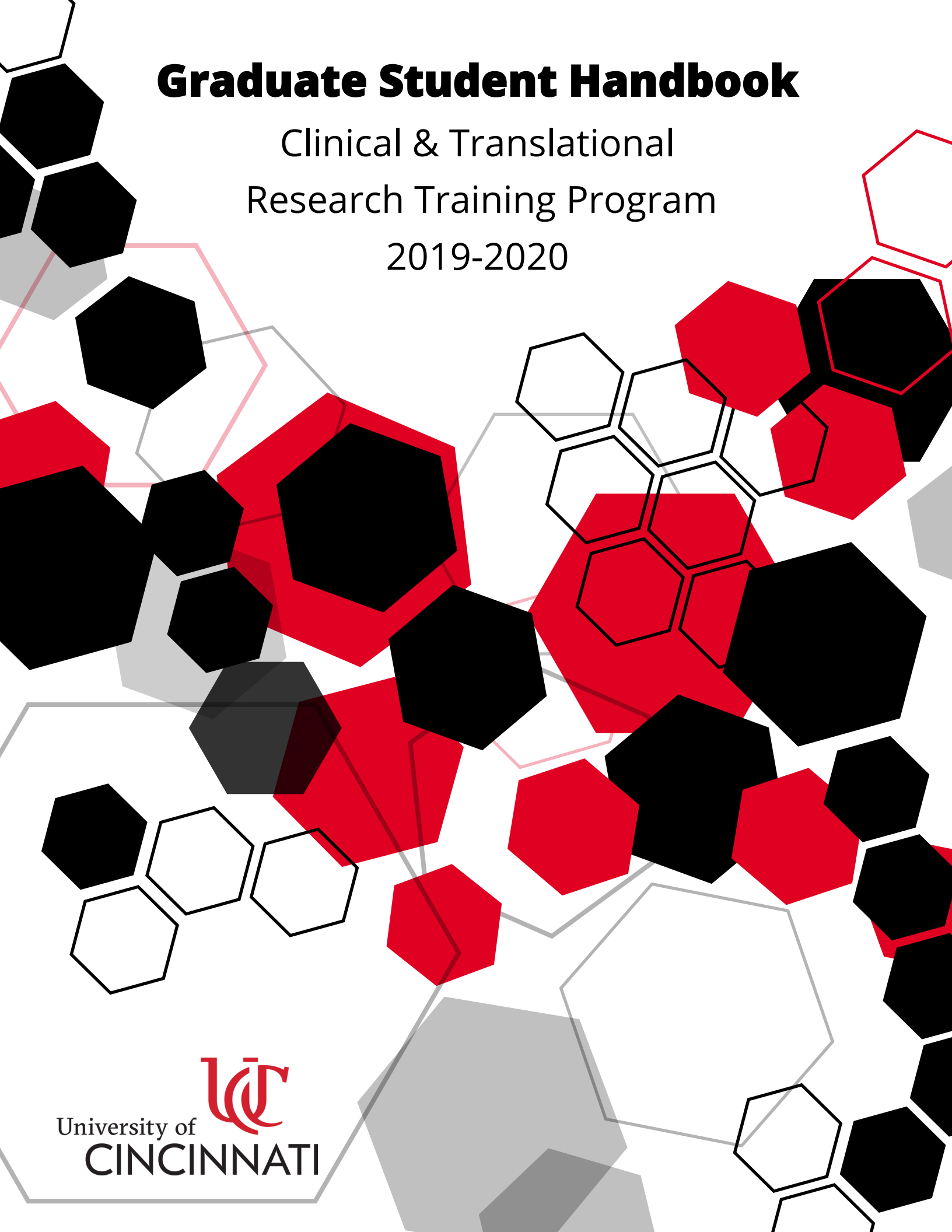
Graduate Student Handbook

Clinical & Translational
Research Training Program
2019-2020



University of CINCINNATI

Welcome to the Clinical & Translational Research Training Program!

The Clinical & Translational Research (CTR) graduate program offers two Master of Science (MS) degree tracks (a Principal Investigator track and a Clinical Research Professionals track) and a Graduate Certificate in CTR. The CTR graduate program falls under the Center for Clinical & Translational Science & Training (CCTST), and its academic home is in the UC College of Medicine, Department of Environmental Health.

The Master of Science in Clinical & Translational Research - Principal Investigator (MSCTR-PI) track is designed to provide clinical professionals (physicians, nurses and other terminal degree clinical professionals) with the necessary preparation for successful career development and independent investigator awards. The MSCTR-PI track emphasizes specific training in clinical epidemiology/clinical effectiveness, molecular epidemiology, clinical trials, quality improvement, informatics, and translational research that will enable clinicians and staff to translate scientific advances into applications for improved clinical practice and human health.

The Master of Science in Clinical & Translational Research - Clinical Research Professionals track (MSCTR-CRP) is designed specifically for clinical research professionals who coordinate, manage, and lead collaborative research projects and clinical trials. The program provides a strong foundation in research methodology and program/project management, including training in research ethics and the Institutional Review Board (IRB) process. The disciplinary purpose and ultimate goal of the program is to provide clinical professionals with the necessary preparation for successful careers in clinical research.

The Graduate Certificate program gives students more of an introduction to the field of CTR, with basic coursework in epidemiology, statistics, and research ethics.

Please contact us with any questions or concerns:

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Graduate Certificate in Clinical & Translational Research

The Graduate Certificate program consists of 10 credit hours. Students can enroll in any term to complete the program at their own pace. The Certificate can also be earned in an 8-week summer session.

Qualified applicants include:

- Fellows and junior faculty interested in collaborating in research, or fellows/junior faculty just launching their career as clinical/translational researchers
- Health science students in the Colleges of Medicine, Pharmacy, Nursing, and Allied Health Sciences
- Basic science researchers crossing over into clinical translation
- Residents
- Post-doctoral fellows
- Health science professionals

Required courses (6-7 credit hours):

Course #	Course Title	Credit hours	Offered
BE-7022	Introduction to Biostatistics	3	Fall Spring/Summer*
BE-7076	Introduction to Epidemiology	2	Fall/Spring Summer*
BE-7067 GNTD-7003	Scientific Integrity **or** Ethics in Research	1-2 1	Summer* Spring

course is offered online

Elective courses (minimum 3-4 credits hours):

The following electives are available online and recommended for Certificate students, but any course offered with a BE course code will be accepted. Electives taken outside of this course code must be approved by the program director.

Course #	Course Title	Credit hours	Offered
BE-7071	Quality Improvement & Patient Safety	1	Fall
BE-7011	Statistical Computation & Software	1	Summer/Fall
BE-9070	Survey of Clinical & Translational Research	1	Summer/Fall
BE-8076	Successful Scientific Writing	2	Summer
BE-7081	IRB Submission Process for Researchers	1	Summer
BE-8069	Study Design & Analysis	2	Fall
ENV-8091	Non-Thesis Research	1-2	Any Semester

Graduate Certificate in CTR Graduation Checklist

Student Name_____

M#_____

Core Courses	
☐ Introduction to Biostatistics	Credit hours_____
☐ Introduction to Epidemiology	Credit hours_____
☐ Scientific Integrity or Ethics in Research	Credit hours_____

Elective Courses	
☐ _____	Credit hours _____
☐ _____	Credit hours _____
☐ _____	Credit hours _____
☐ _____	Credit hours _____
☐ _____	Credit hours _____

Minimum GPA (≥ 3.0)
☐ _____

Total Credit Hours (≥ 10 credit hours)
☐ _____

☐ Student Applied to Graduate _____

☐ Student Certified by Program _____

☐ Student Certified by Graduate School _____

Master of Science in Clinical & Translational Research

The educational objective of the Master of Science in Clinical & Translational Research (MSCTR) is to train the clinical research workforce of the future, preparing graduates for careers in academic health centers, private clinical research organizations, research non-profits, or government agencies. The MSCTR offers two-degree tracks: one for principal investigators (MSCTR-PI) who design and conduct clinical studies in their areas of practice and special interest and a second designed specifically for clinical research professionals (MSCTR-CRP) who coordinate, manage, and lead collaborative research projects and clinical trials. Both tracks will emphasize team science, research integrity, and provide a strong foundation in research methodology and management, culminating in a capstone or thesis project.

Principal Investigator (MSCTR-PI) Track

The MSCTR-PI program trains clinical professionals (physicians, nurses, and other terminal degree clinical professionals) to become independent investigators and to provide them with training necessary to prepare successful career development and independent investigator awards. The disciplinary purpose and ultimate goal of the program is to move practitioners from the realm of personal clinical experience to objective evidence. Successful graduates of the program will acquire the methodological skills to conduct independent and collaborative clinical studies in their special areas of practice and interest.

Please note the program's Curriculum Committee examines and evaluates all courses regularly, so changes may occur.

Required Courses for the MSCTR PI Track

Course #	Course Title	Credits	Offered
BE-7022	Introduction to Biostatistics	3	Fall Spring/Summer*
BE-7076	Introduction to Epidemiology	2	Fall/Spring Summer*
BE-9075	Design & Management of Field Studies in Epidemiology	3	Spring
BE-9066	Clinical Research Scholars Seminar	1	Spring
	Research Ethics		
	Choose one of the following:		
BE-7067	Scientific Integrity	1-2	Summer*
GNTD-7003	Ethics in Research	1	Spring
	Statistical Programming		
	Choose one of the following:		
BE-8083	Data Analysis with R and SAS	3	Fall
BE-7024	Computational Statistics (SAS and R)	3	Fall
PHDD-8060	Statistical Principles in Clinical Research (JMP)	3	Fall
	Regression Analysis		
	Choose one of the following:		
BE-7023	Advanced Biostatistics (R)	3	Fall
BE-7088	Regression Analysis (SAS)	3	Spring
EDST-7011	Statistical Data Analysis II (online any semester) (SPSS or R)	3	Fall/Spring/Summer*
	Advanced Methods		
	Choose one of the following:		
BE-8069	Study Design & Analysis (online)	2	Fall*
BE-7068C	Decision-Analysis and Cost-Effectiveness Analysis	3	Spring
BE-9061C	Meta-Analysis	3	Fall
BE-7066	Principles of Clinical Trials	3	Fall

BE-7025	Comparative Effectiveness Research & Patient-Centered Outcomes Research	2	Fall
BE-8062	Introduction to Medical Informatics **or** *any advanced methods course offered under the BE course code*	3	Fall
	Culmination		
ENV-7091	Master's Thesis Research	2	Fall/Spring/Summer
	Electives *Students may fulfil the remaining elective course credit hours by completing an optional focus area, additional elective courses of choice, and/or a maximum of 6 credit hours of non-thesis research (ENV-8091). Elective courses outside of the department need to be approved by the Program Director.*	8-10	
	Total	**30**	

***course is offered online**

MSCTR-PI Focus Areas

Students can specialize in Clinical Epidemiology & Clinical Effectiveness, Translational Research, Molecular Epidemiology, Clinical Trials, Research Informatics (T1 or T2), or Quality Improvement. Additional coursework is required for each of these Focus Areas (see below). Students may select one of the five specialized Focus Areas to fulfill their remaining elective credits. The tracks below were designed by clinical research experts to provide specialty training in each of the five focus areas. ***Students do not have to complete a track to complete the MS program***. If students wish to 'specialize' in a particular focus area, they are encouraged to meet with the MS faculty leadership, Aimin Chen or Pat Ryan, to discuss courses, research opportunities, and career pathways.

Clinical Epidemiology & Clinical Effectiveness

Using a combination of didactic material and seminars, the Clinical Epidemiology/Clinical Effectiveness Focus Area enables participants to develop the analytic and quantitative skills necessary to conduct clinical research. The required courses will provide training in traditional epidemiologic research methods including study design and analysis. Additional courses will address the relative merits of various designs; the design and conduct of clinical trials; the health decision sciences; health services research; informatics; questionnaire development; and other clinical and outcomes research topics. Didactic sessions will be supplemented by small discussion groups, practical exercises, and invited guest speakers.

Additional Required Courses for Clinical Epidemiology/Clinical Effectiveness (10-12 credits)

Course #	Course Title	Credit Hours	Offered
BE-7066	Principles of Clinical Trials	3	Fall
BE-7088	Regression Analysis	3	Spring
	Choose two:		
BE-8062	Introduction to Medical Informatics	3	Fall
BE-7071	Quality Improvement & Patient Safety (online)	1	Fall*
BE-7068	Decision Analysis & Cost-Effectiveness Analysis	3	Spring

Translational Research

The Translational Research Focus Area is intended for physicians who plan to be involved in developing IND-type early phase clinical trials. This area includes preclinical and early phase clinical testing of new therapeutic or diagnostic reagents, as well as collection and handling of patient specimens. Students will take courses in the College of Pharmacy geared towards clinical trials and regulatory affairs and in Developmental Biology, Disease and Development. Two new courses have been created for this focus area: Patient Specimen Methods

and Disease Specific Translational Research. To gain a more solid understanding of the molecular mechanisms underlying diseases, trainees may fill the elective hours with the molecular biology series offered at UC each year. Ideally, research projects will encompass late preclinical or early clinical projects.

Additional Required Courses for Translational Research (13 credits)

Course #	Course Title	Credit Hours	Offered
PHDD-8060	Statistical Principles in Clinical Research	3	Fall
PHDD-8030	Pre-Clinical/Non-Clinical Studies for IND Approval	3	Spring
BE-9073	Molecular Epidemiology	2	Spring
DB-9087	Disease & Development	2	Spring (even years)
CS-7099	Introduction to Medical Informatics	3	Fall

Molecular Epidemiology

We define molecular epidemiology as the use of biological markers in epidemiologic research to evaluate events occurring at the physiologic, cellular, subcellular, and molecular levels. The Molecular Epidemiology Focus Area encompasses biomarker, cancer, and genetic epidemiology. The overall objective of the Molecular Epidemiology Focus Area is to establish an interdisciplinary training program in molecular epidemiology for clinicians seeking an advanced degree (MS or PhD). With the requisite didactic coursework students will develop the knowledge base and conceptual framework of scientific inquiry to foster independent research careers in molecular epidemiology. The Molecular Epidemiology Focus Area builds on research, teaching, and mentoring strength within the Center for Environmental Genetics, comprised of interdisciplinary investigators of world-class scientists in the Department of Environmental Health.

Additional Required Courses for Molecular Epidemiology (11 credits)

Course #	Course Title	Credit Hours	Offered
BE-9073	Molecular Epidemiology	2	Spring
GNTD-7001	Molecular & Cellular Biology	3	Fall
BE-7088	Regression Analysis	3	Spring
	Choose two:		
CB-8080	Biology of Cancer	3	Spring
GC-7020	Human Genetics	3	Fall

Clinical Trials

The overall objective of the Clinical Trials Focus Area is to train clinical researchers interested in clinical trials and translational research. Trainees concentrating in Clinical Trials will learn the fundamentals of clinical trials and the drug/device development process, including the responsible conduct of research, the phases of clinical trials, and regulatory affairs. A unique aspect of the curriculum is that UC professors team with industry leaders to teach several of the courses, so that students get a “real world” experience. The electives for this Focus Area are taught through the College of Pharmacy.

These trainees gain the skills required to effectively complete investigator-initiated, IND-directed early phase clinical trials. Trainees learn critical aspects of study design and conduct, mechanisms of financial support, and data analysis and publication. A basic understanding of laboratory methods, data analysis, and the molecular basis of disease is critical to bridge laboratory and clinical research and is therefore included in the training. The curriculum covers training in pre-clinical efficacy and toxicology studies that are required to support early phase clinical trials. In addition, regulatory affairs issues unique to translational research are covered.

Additional Required Courses for Clinical Trials (15 credits)

Course #	Course Title	Credit Hours	Offered
BE-7066	Principles of Clinical Trials	3	Fall
PHDD-8010	Global Regulatory & Development Strategies of Drugs & Medical Devices	3	Fall
PHDD-8050	Phase I/II Clinical Trials Research & Design	3	Spring
PHDD-8070	Phase III/IV Clinical Trials & Research	3	Spring
PHDD-8040	Development & Manufacturing of Drug Products & Medical Devices	3	Fall

Research Informatics

The Research Informatics Focus Area has itself been divided into two separate areas of focus. The first focuses on the translation of basic science findings to clinical research studies and is titled: the *Translational Research Informatics Focus*. The second focuses on the translation of research findings into clinical and community practice and is titled: the *Clinical Research Informatics Focus*. While we specify required and elective courses below, our intent is that the student work closely with (her/his) advisors and mentors to select the appropriate courses. In consultation with advisors, students may also wish to take additional courses not listed on the track descriptions below.

Additional Required Courses for Translational Research Informatics (Minimum 13-14 Credits)

Course #	Course Title	Credit Hours	Offered
BE-8062	Introduction to Medical Informatics	3	Fall
GNTD-8001C	Introduction to Functional Genomics	3	Spring
	Choose three:		
CS-7099	Introduction to Bioinformatics	3	Spring
BE-7068	Decision Analysis & Cost-Effectiveness Analysis	3	Spring
IS-7030	Data Modeling *(first 7 weeks of the semester)*	2	Fall
IS-7032	Database Design *(second 7 weeks of the semester)*	2	Fall

Additional Required Courses for Clinical Research Informatics (Minimum 11-14 Credits)

Course #	Course Title	Credit Hours	Offered
BE-8062	Introduction to Medical Informatics	3	Fall
BE-7068	Decision Analysis & Cost-Effectiveness Analysis	3	Spring
	Choose three:		
BE-7071	Quality Improvement & Patient Safety	1	Fall*
IS-7030	Data Modeling *(first 7 weeks of the semester)*	2	Fall
IS-7032	Database Design *(second 7 weeks of the semester)*	2	Fall
IS-7034	Business Intelligence Prerequisite: IS-7032	2	Spring
IS-7036	Advanced Business Intelligence Prerequisite: IS-7034	2	Spring
CS-6033	Artificial Intelligence	3	Fall
CS-6052	Intelligent Data Analysis *(odd years)*	3	Spring

Quality Improvement

The Quality Improvement Focus Area prepares trainees to transform health and healthcare delivery by creating effective healthcare delivery system interventions that can be disseminated into real-world practice settings, resulting in improved health outcomes. The coursework in this focus area will provide strong methodologic training in health services research and quality-improvement methods. Trainees will take coursework in both quantitative and qualitative methods to improve effectiveness, efficiency, and safety of healthcare delivery processes.

Additional Required Courses for Quality Improvement (13 Credits)

Course #	Course Title	Credit Hours	Offered
BE-8062	Introduction to Medical Informatics	3	Fall
BE-7066	Principles of Clinical Trials	3	Fall
BE-9061C	Meta-Analysis	3	Fall
BE-7068C	Decision Analysis & Cost-Effectiveness Analysis	3	Spring
BE-7071	Quality Improvement & Patient Safety (online)	1	Fall

Dr. Nick Newman, an alumnus of the MS program, presenting information about lead at a community meeting in Lower Price Hill.

Clinical Research Professionals (MSCTR-CRP) Track

Students with or without experience in clinical research who enroll in the MSCTR-CRP track will gain formal training in the management of clinical research, improving their abilities to coordinate and lead studies in a variety of settings, including academic health centers and pharmaceutical companies. The CRP core curriculum consists of coursework in research ethics, research methods, program/project management, and a thesis or capstone project.

Required Courses for the MSCTR CRP Track

Course #	Course Title	Credits	Offered
BE-9064	Clinical Research Professionals Seminar	2	Fall 2020
BE-8069	Study Design & Analysis	2	Fall 2019*
BE-7066	Principles of Clinical Trials	3	Fall 2019
BE-8082	Research Methods for Human Population Studies	3	Spring 2019
BE-7081	IRB Process & Protocol for Researchers	1	Summer 2020*
	Research Ethics **Choose one of the following:**		
BE-7067	Scientific Integrity	1	Summer 2020*
GNTD-7003	Ethics in Research	1	Spring 2020
	Regulatory Affairs **Choose one of the following:**		
BE-7035	Preclinical Regulatory Overview	2	Fall 2020
BE-7036	Clinical Research Regulatory Overview	3	Fall 2020
	Project/Data Management **Choose one of the following:**		
BE-7033	Project Management & Evaluation	2	Spring 2020
BE-7050	Clinical Data Management	2	TBD
	Culmination **Choose one of the following:**		
ENV-7091	Master's Thesis Research	2	Fall/Spring/Summer
BE-7092	CRP Capstone Project	2	Fall/Spring/Summer
	Electives *Students may fulfil the remaining elective course credit hours by completing an optional focus area, additional elective courses of choice, and/or a maximum of 6 credit hours of non-thesis research (ENV-8091). Elective courses outside of the department need to be approved by the Program Director.*	11-12	Varied
		Total	**30**

course is offered online

Students can specialize in Clinical Trials, Generalist, or Community-Engaged Research. Additional coursework is required for each of these focus areas (see below). Students may select one of the specialized focus areas to fulfill their remaining credits, or they can take electives or complete research. ***Students do not have to complete a focus area to complete the MS program***. If students wish to 'specialize' in a particular focus area, they are encouraged to meet with the MS faculty leadership, Aimin Chen or Patrick Ryan, to discuss courses, research opportunities, and career pathways.

MSCTR-CRP Focus Areas

Clinical Trials

The overall objective of the Clinical Trials Focus Area is to train clinical researcher professionals interested in clinical trials and translational research. Trainees concentrating in Clinical Trials will learn the fundamentals of clinical trials and the drug/device development process, including the responsible conduct of research and regulatory affairs. A unique aspect of the curriculum is that UC professors team with industry leaders to teach several of the courses, so that students get a "real world" experience. The electives for this Focus Area are taught through the College of Pharmacy.

Additional Required Courses for Clinical Trials (6 credits)

Course #	Course Title	Credit Hours	Offered
PHDD-8010	Global Regulatory & Development Strategies of Drugs & Medical Devices	3	Fall 2019
PHDD-8040	Development & Manufacturing of Drug Products & Medical Devices	3	Spring 2020

Generalist

The goal of the Generalist Focus Area is to train clinical research professionals interested in key factors at play within clinical research, such as finance, economics, and decision making. Trainees concentrating in the Generalist focus area will learn the fundamentals of clinical research, giving them the skills and knowledge to work in a variety of clinical research settings. This track takes advantage of courses offered at three other Colleges: Pharmacy, Nursing, and Allied Health.

Required Courses for Generalist (6 credits)

Course #	Course Title	Credit Hours	Offered
HCA-7041	Evidence-Based Decision Making	3	Fall 2019*
	Choose one:		
NDNP-8010	Finance & Economics of Healthcare	3	Fall 2019*
PHDD-8080	Pharmaceutical Economics & Management	3	Spring 2020

Community-Engaged Research

The goal of the Community-Engaged Research Focus Area is to provide clinical research professionals with an introduction to working with community members through a research-based partnership, and ways in which they can incorporate participatory methodologies into their community-engaged research study designs. This Focus Area will touch base on techniques used for research partnership formation, evaluation of partnerships, and dissemination of results to lay audiences.

Required Courses for Community-Engaged Research (7-8 credits)

Course #	Course Title	Credit Hours	Offered
BE-7031	Communicating Your Science	2	Fall 2019
EDST-7045	Community-Based Participatory Research	3	Summer 2020
	Choose one:		
BE-7025	Comparative Effectiveness Research/Patient- Centered Outcomes Research	2	Fall 2019
EDST-8021	Action Research I	3	Fall 2019
EDST-8022	Action Research II	3	Spring 2020

Statement of Intent & Master's Thesis Guidelines

Master of Science Thesis Requirement
(Required for MSCTR-PI track. MSCTR-CRP track requires either a thesis or a capstone.)

The MS thesis is intended to demonstrate the student's ability to communicate and evaluate critically. The thesis needs to be the result of independent research. Information concerning the thesis format and mechanics of preparing the final document can be found online at www.grad.uc.edu.

Thesis research may be part of the ongoing work of the thesis laboratory but must be separately identifiable. The thesis research should reflect advisor/mentor guidance but mainly be the independent work of the student. A thesis may be written in the form of a publishable research paper, conforming to the publication guidelines of the student's journal of choice (e.g., JAMA, Pediatrics, AJE, etc). The research must be conducted while the student is enrolled in the program and the student must be the first author of the manuscript. Students must place an embargo on the thesis if they submit their thesis prior to publication of the manuscript (see below for further instructions).

After approval of the original topic by the Thesis Committee in the form of the Statement of Intent (SOI), any major change from one thesis topic to another is not permitted without approval of the new thesis topic by the Thesis Committee. In agreement with the function of the Thesis Committee, as specified by the rules of the University of Cincinnati Graduate School, any decisions about the quantity and quality of the work done are the responsibility of the Thesis Committee.

Once the SOI is approved, students should make continuous progress on the thesis towards graduation. Thesis Committee members should have ample opportunity to review student thesis work at all stages to ensure the project is on track. A final draft of the thesis should be submitted for Committee review at least 1 month before the graduation deadline.

After the student leaves the University, the thesis research results may be used as the basis for continuing investigations by the student and/or by the laboratory in which the thesis research was done. The student and the laboratory are entitled to retain copies of the data and analyses for their use.

The University of Cincinnati Electronic Thesis or Dissertation (ETD) website has all the details you'll need to submit your final thesis: http://grad.uc.edu/student-life/etd/formatting.html. In short, you will need to submit your full thesis in PDF form to OhioLINK following the directions on the ETD website, along with a scanned PDF of your fully signed Committee Approval form. Please see www.grad.uc.edu for thesis submission deadlines by semester.

If a student has not published their thesis prior to graduating, they are strongly recommended to embargo their thesis. The student can request an embargo on the thesis for two years initially, with the option of extending the embargo a third year. An embargo is simply a hold on publishing your thesis in the Ohio library system (OhioLINK). If the plan to submit your thesis in part or whole for publication in a journal, it is vital that you embargo your work for a period of time. Some journals still consider a thesis that is published on the internet a "publication." In order to avoid the fact or appearance of a "duplicate" publication it is important to embargo your document. You request an embargo electronically when you upload your thesis for final approval by your chairperson. As a further protection, you should acknowledge in any submitted manuscripts based upon your graduate research that the work was completed in partial fulfillment of the requirements for the MS in Clinical

and Translational Research (see suggested acknowledgment below). See your advisor if you have any questions regarding the embargo of your work.

Students are strongly encouraged to publish their theses. Publication of the thesis can occur at any time during the program. **If you publish part or all of your thesis in a journal, you should add the following acknowledgement to your publication:**

"This work was completed in partial fulfillment of the Master of Science degree in Clinical and Translational Research in the Division of Epidemiology, University of Cincinnati College of Medicine." **Also acknowledge any grant support you received as you completed your project. Students in the MS in Clinical and Translational Research training program should reference the CTSA:** *"This publication was supported by an Institutional Clinical and Translational Science Award, NIH/NCATS 1UL1TR001425. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH."*

Scholarly Oversight Committee (SOC)

Many MS students are concurrently completing fellowships at CCHMC. Fellowships that are accredited by the American Board of Pediatrics (ABP) require a Scholarly Oversight Committee for fellows. As described on the ABP website (https://www.abp.org/content/scholarly-activity):
"The Scholarship Oversight Committee should consist of three or more individuals, at least one of whom is based outside the subspecialty discipline; the fellowship program director may serve as a trainee's mentor and participate in the activities of the oversight committee, but should not be a standing (i.e., voting) member. This committee will:

- Determine whether a specific activity is appropriate to meet the ABP guidelines for scholarly activity
- Determine a course of preparation beyond the core fellowship curriculum to ensure successful completion of the project
- Evaluate the fellow's progress as related to scholarly activity
- Meet with the fellow early in the training period and regularly thereafter
- Require the fellow to present/defend the project related to his/her scholarly activity
- Advise the program director on the fellow's progress and assess whether the fellow has satisfactorily met the guidelines associated with the requirement for active participation in scholarly activities"

Students who do not already have an SOC as part of their fellowship are strongly encouraged to arrange their own.

Thesis Committee

The Thesis Committee is typically composed of your research mentor(s), your academic advisor (see page 20), and a biostatistician. If students have an SOC (see above), it is expected that there will overlap between the SOC and the Thesis Committee, i.e., that several members of your SOC will also serve on your Thesis Committee. The academic advisor (see page 20) is the chair of the Thesis Committee. The advisor is also a voting member of the Thesis Committee. Typically, your primary research mentor should be the second committee member, and the biostatistician on your thesis project is the third. According to the rules of the Graduate School, the Thesis Committee should be composed of at least two full-time faculty members with professorial rank, at least one of whom is a member of the All-University Graduate Faculty. Committee members outside of the University are subject to review and approval by the Graduate School. The final judgment on acceptability of the thesis will be

made by the Thesis Committee, by a unanimous vote if there are only two members, or else with no more than one dissenting vote.

Thesis Statement of Intent (SOI)

The Statement of Intent (SOI) is your thesis proposal. You should work with your research mentor to choose an appropriate thesis research project. As soon as you have selected your thesis project, you should submit your SOI to your Thesis Committee, typically via email. Your Thesis Committee should review your SOI for appropriateness of methods, publishability, and feasibility. The SOI should be submitted for the Thesis Committee's review early in the thesis project's timetable (i.e., before the majority of the data are collected). A majority of the Thesis Committee members must approve of the SOI and sign the SOI Approval Form.)

The SOI should be a brief (not to exceed three single-spaced pages excluding signed SOI approval form, references, and time table) description of the proposed thesis. The SOI will be based on NIH PHS398 guidance for proposals. Follow NIH requirements for margins and font (11 pt Arial font, single-spaced, ½" margins). The following headings need to be used when writing the statement.

A) Significance
   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved
   - Incorporate your relevant literature review as background and supporting information in this section.
   - Address the scientific premise of the study.
   - State clearly the public health significance of your proposal and once successful how your project will positively impact/improve public health.

B) Innovation
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms
   - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions
   - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions

C) Approach
   - Clearly state the hypothesis and specific aims.
   - A clear description of the study design. Describe the overall strategy, methodology, and analyses to be used to accomplish the aims of your project
   - A clear description of the study population including inclusion/exclusion criteria
   - A clear definition of outcome and predictive variables
   - Describe the methods taken to ensure scientific rigor, i.e., descriptions of research tools and their reliability/validity, and methods to address quality control and quality assurance. Include information on how the data will be collected, analyzed, and interpreted. Point out any procedures, situations, or materials, if any, that may be hazardous to personnel and

precautions to be exercised.
- Include statistical analysis, including sample size
- Include a limitations section: description of potential bias – stating potential confounders, such as sex, age, weight, and other underlying health conditions and how these will be handled.
- Discuss potential problems, alternative strategies, and benchmarks/timelines for tasks to be completed to achieve the aims.

D) Timeline
E) Note concerning IRB
F) References

The statement should indicate that the work will demonstrate your powers of critical evaluation. The SOI must include a cover memo providing details on your name, the project title, and members of the Thesis Committee with signatures. Please email rachel.meyer@uc.edu for more information. Samples of previous SOIs are available from the CTR program office, via email. A copy of the signed SOI Approval Form must be filed with the CTR program office.

SOI Submission Deadline

Ideally, your SOI should be approved and submitted by the end of your first year in the MS program (after approximately two semesters of coursework).

At the very latest, the SOI must be approved and submitted to the CTR program office via email before the last day of the term preceding the semester in which you plan to graduate. Dates are provided below.

Graduation Semester	Statement of Intent Deadline
Fall 2019	August 10, 2019
Spring 2020	December 14, 2019
Summer 2020	April 30, 2020

Master of Science Capstone Requirement:
(MSCTR-CRP Track only)

The capstone project is designed for MSCTR-CRP students to complete their culminating experience in clinical research management. The goal of the Capstone is to demonstrate your ability to synthesize and integrate your knowledge of the MSCTR-CRP core learning outcomes. The Capstone project may take many forms, such as a practice-based, evaluation of processes, or training development.

Regardless of form, students are required to produce a high-quality written product that is appropriate for their educational and professional objectives. Written products may include the following: program evaluation report, expanded project proposal, grant proposal, training manual, policy statement, clinical trial protocol, etc. Ideally, the written product is developed and delivered in a manner that is useful to external stakeholders. The project must be the independent work of the student, not a product of the student's work environment.

Students are eligible to register for the Capstone course credits after completing 15 credit hours of MSCTR-CRP courses. Students completing a Capstone will demonstrate their ability to understand a problem, articulate

solutions, think critically about a clinical and translational research project or issue, and demonstrate learning in written form.

Examples of a capstone project include:

- Evaluating clinical staff's knowledge of purpose and requirements for clinical trials and improving awareness with clinical staff
- Improving participant understanding of study requirements and follow up.
- Creating tools to assist CRPs on investigator initiated trials; provide info to participants that is at the correct reading level and compliant with the study
- Cultural awareness in clinical trials
- Educational program event for CRPs (e.g., presentation of a half-day topic on advances and innovations in clinical trials
- Electronic consent development
- Promoting cost recovery in clinical trials (e.g., best practices, evaluation of process at site and improvements to process)
- Improving CRP's understanding of implications of genetics and genetic testing in clinical trials
- Data management best practices (e.g., issues related to double data entry, setting up databases for auditing, and error prevention)
- Handling co-enrollment in studies
- Strategies for Exemption from Informed Consent (EFIC)

Timeline:

**Due dates for required documents and assignments will be posted on Blackboard.*

MSCTR-CRP required dates for Capstone Submission:

Beginning of semester	Submit Capstone form and proposal.
4 weeks before classes end	Student must submit first draft via Blackboard for Director/Associate Director review.
2 weeks before classes end	Draft returned to student for final revisions.
1 week before classes end	Student must submit final documents via Blackboard for faculty Director/Associate Director final evaluation and grading.
Last day of semester	Student must submit the final Capstone project with signature page via Blackboard.

Academic Policies for the MS & Certificate Programs

Advisor & Course of Study

The program coordinator is the primary advisor for most students in all CTR programs. If a student needs advising from a faculty member, students whose last name begins with A-L are assigned to Dr. Aimin Chen and students whose last name begins with M-Z are assigned to Dr. Patrick Ryan. If appropriate, a different advisor may be requested at a later date. In the event of a change in advisor, the student shall send a communication to the CTR program office that includes the signatures of both the assigned and proposed advisor, as well as the program director indicating concurrence.

Students' course plans should be developed in consultation with program staff and, when necessary, faculty leadership. The student's program is subject to approval by the program faculty and must show a reasonable degree of concentration on interrelated subjects.

Credit Hours

To graduate with a Master of Science degree in CTR, students must complete a minimum of 30 graduate credit hours (including 2 thesis credits for MSCTR-PI track, and 2 thesis or capstone credits for MSCTR-CRP track). To graduate with a Certificate in CTR, students must complete a minimum of 10 graduate credit hours.

Origin of Credits/Student Status	Max Number of Credits Transferred
Previous credits were taken at UC when student was non-matriculated	3 credits for Certificate, 12 credits for MSCTR programs **Pending Program Director approval*
Previous credits were taken at UC when student was matriculated into another program	Up to 1/3 of Certificate or MSCTR requirements (3 credits for CCTR, 10 credits for MSCTR programs) **Pending Program Director approval*
Previous credits were taken at another institution when student was non-matriculated or matriculated	Up to 1/3 of Certificate or MSCTR requirements (3 credits for Certificate, 10 credits for MSCTR programs) **Pending Program Director & Graduate School approval*

Credits earned in a degree higher than the one the student is completing at UC cannot be transferred. For example, credits taken towards an MS program cannot be applied to the Certificate and credits taken towards a PhD cannot be applied to the MSCTR programs. Students who want to continue from the Certificate and earn their MSCTR must formally apply to and be accepted into one of the MSCTR programs. Once accepted, the Certificate credits will be automatically applied toward the chosen MSCTR program.

Research Credits

Students matriculated into the MS or Certificate programs can earn academic credit for their independent research projects. Independent research projects must be documented and pre-approved, then verified, in order to receive credit. Typical projects completed for credit include:

- preparing and presenting an abstract or poster at a national conference,
- writing and/or submitting a manuscript for publication,
- writing and/or submitting a grant proposal,
- preparing and/or submitting an IRB submission, and

- ongoing work related to a student's Master's thesis

Other projects with deliverables could be acceptable provided they are relevant to the nature of the research project and approved by a research mentor and/or academic advisor.

The purpose of the process outlined below is to ensure student research meets the legitimacy and quality standards that merit graduate academic credit. The forms required outline the research project plan, document the number of academic credit hours requested, and must be signed by the student, Research Mentor, AND Academic Advisor. The Research Mentor is selected by the student, and is responsible for monitoring the progress of the research over the semester. The Academic Advisor is responsible for approving the research plan, reviewing the student's work, and assigning a grade at the end of the semester. It is permissible for the student's Academic Advisor to also serve as his or her Research Mentor.

Students who wish to earn academic credit for their independent research projects must:

1. Complete a Research Credit Pre-Approval Form (http://med.uc.edu/eh/divisions/epi/student-resources) and obtain the signatures of BOTH their Research Mentor monitoring the project AND their assigned Academic Advisor within the CTR program. Submit this form to rachel.meyer@uc.edu, who will then give you permission to register for the credits in Catalyst.

2. Register for the Research credits using the following course codes:

    - ENV-7091: Thesis Research
    - ENV-8091: General (non-thesis) Research

3. Complete a Research Credit Verification Form (http://med.uc.edu/eh/divisions/epi/student-resources), signed by BOTH the Research Mentor AND the Academic Advisor listed on the Pre-Approval Form submitted earlier in the semester, by the end of the term in order to receive a passing grade. Submit to rachel.meyer@uc.edu.

Both forms are also available on our website. Students are responsible for documenting their work during the semester in which they are registered for research credits. Verification forms can also be submitted to rachel.meyer@uc.edu.

If there is any question about the quality of work completed for research credit, the academic advisor is responsible for evaluating the student's work and providing an appropriate grade at the conclusion of the semester.

Minimum Academic Performance

Students are considered full-time when they are registered for 10-18 graduate credits per semester. Students receiving a University Graduate Scholarship (UGS) must be registered for 12 graduate credit hours for each semester for which they are receiving support. If a student is registered for at least 1 graduate credit, he or she will maintain graduate student status throughout the entire academic year, fall through summer.

In order to obtain a MS or Certificate, a student must maintain a B average (3.0) or better. In addition, at least 2/3 of the minimum graduate credits necessary for the degree must be at a level of B or higher. Students cannot

graduate with I or NG grades in graduate level courses on their records. They should keep their advisors and the program office well-informed of their degree intentions.

Academic Misconduct

Students in the CTR programs are held to the highest code of academic honesty. Academic misconduct or dishonesty is defined in the University of Cincinnati Student Code of Conduct and includes, but is not limited to, acts of cheating, plagiarism, falsification, and misappropriation of credit. The Student Code of Conduct (www.uc.edu/conduct/Code_of_Conduct.html) defines behavior expected of all University of Cincinnati students. It is each student's responsibility to know and comply with the University's Student Code of Conduct. Disciplinary procedures are explained in a step-by-step manner, and the procedures for appeal of decisions are stated.

Maintaining Active Student Status

Students will need to register for at least 1 credit hour per academic year to maintain active status. To maintain status as a graduate student and thus be eligible for a graduate degree, students must register for at least 1 credit each academic year. In addition, students are required to register for at least 1 credit during each semester that they wish to use University resources (excluding summer semester).

Time Limitations

A student pursuing a program leading to a Master's degree must complete all requirements no later than 5 years from the date of matriculation in that degree program. Under extenuating circumstances, students may petition the Associate Dean of the Graduate School, through their program, for an extension of the time limit. Petitions must be submitted on the approved form available online at: www.grad.uc.edu. Students who have not been enrolled in classes for more than three years are not eligible for reinstatement and must reapply for admission to the University. Forms are located online at www.grad.uc.edu.

Graduation

Any student intending to receive a graduate degree is responsible for completing the "Online Graduation Application" at: www.grad.uc.edu and ensuring that the procedures are carried out and the indicated forms are submitted electronically to the Graduate School.

- **Cap and Gown** - may be purchased or rented at the University Bookstore.
- **Incomplete (I)** and **"No Grade" (NG) Grades** - Notification of removal of all **I** and **NG** grades must be submitted prior to the student's graduation.
- **Credit Hours** - Completion of the required semester credit hours for the degree.
- **Departmental Requirements** – Students must complete all departmental requirements for the degree. Any graduate student who expects to receive a degree at any of the three University commencements must make a formal application for the degree. Check www.grad.uc.edu for deadlines for each semester.

Frequently Asked Questions

Q. Can I take courses without officially entering the program as a degree-seeking student?
A. Yes, you can take courses as a non-matriculated student. Step-by-step directions on how to do this can be found here. Please note that only 12 non-matriculated credits can be applied to the MSCTR programs (5 to the Certificate) once you are accepted into a program. Please note: Non-matriculated students cannot earn Mentored Research credits.

Q. How do I register for courses before I am officially accepted into the program?
A. If you want to take courses before you are officially accepted, you should register as a non-matriculated student. Step-by-step directions can be found here: http://www.uc.edu/registrar/registrar_forms/basic-data-form-for-non-matriculated-students.html. Please note that the University of Cincinnati will only accept 12 non-matriculated credits upon entering a degree program, so you should not take more than 12 credits before being officially accepted into one of the MSCTR programs (5 for the Certificate).

Q. Can I take courses online?
A. We currently offer the following classes online at least once a year: Introduction to Biostatistics, Introduction to Epidemiology, Statistical Computation & Software, Quality Improvement & Patient Safety, Scientific Integrity, Successful Scientific Writing, Study Design & Analysis, IRB Process & Protocol, and Survey of Clinical & Translational Research. We continue to work at converting our traditional courses to online courses, so continue to check back for updates.

Q. I missed the application deadline listed on the Graduate School website. Can I still apply?
A. The Certificate and the MSCTR programs review applications on a rolling basis throughout the year, so you can apply at any time following the next semester's deadline. For the MS program, you can take up to 12 credits as a non-matriculated student; for the Certificate, you can take up to 5 credits as a non-matriculated student, and these will transfer in if you're officially accepted.

Q. Do you require TOEFL scores?
A. Official TOEFL scores (Institutional code=1833; Department Major Field Code=46) are required, if applicable. A minimum TOEFL score of 600 paper/250 computer test/100 Internet-based is required of all applicants whose native language is not English, unless specifically exempted. The TOEFL requirement is met for applicants who have passed the USMLE or for applicants with medical or graduate degrees earned from accredited universities and colleges in the US, Canada (except Quebec), England, Australia, New Zealand, or other English-speaking countries. Please contact rachel.meyer@uc.edu for TOEFL waiver options.

Q. Which transcripts are required for the application?
A. The MSCTR programs must have an official transcript from all institutions where you received a degree. The Certificate only requires an official transcript from your most recent degree.

Q. How much does the program cost?
A. To graduate from the MSCTR programs, students must complete 30 credits total (including 2 hours of thesis research for the MSCTR-PI track, and 2 hours of thesis research or capstone project for the MSCTR-CRP track). To graduate from the Certificate program, students must complete 10 semester credits. To view UC tuition costs for the current academic year, visit: http://www.uc.edu/bursar.

Q. Where can I find the class call numbers I need for registration?
A. Go to www.onestop.uc.edu, and click on "View Class Offerings." Choose the term, college, and discipline in which you're interested, and you should see information on all the classes currently offered, including course number, call number, and number of credits.

Q. What are the Graduation Certificate in CTR requirements?
A. Students must complete 3 required courses for a total of 6-7 credit hours: Introduction to Epidemiology (online-summer & in-person-fall and spring), Introduction to Biostatistics (online-summer and spring & in-person-fall), and Scientific Integrity/Ethics in Research (online-summer & in-person-spring) and any 3-4 credit hours of elective courses for a total of 10 credit hours.

Q. Can I complete the Graduate Certificate in CTR online?
A. Although the Certificate can be completed entirely online, summer semester is the only term in which we currently offer a full online curriculum and not all CTR classes are offered online. In general, one or two online classes are offered in the fall and spring semesters. Students are welcome to take a mix of both online and in-seat classes to best fit their schedule, interests, and timeline for completion.

Q. How do online classes work?
A. All online classes are housed on Blackboard, UC's online learning site, at canopy.uc.edu. Students should log in to Blackboard using their UC central log in and check their course sites daily for course announcements, assignments, and other postings. Most online classes are made up of a series of modules, lectures with accompanying PowerPoints, audio, and/or video.

Q. Can my independent research count toward the Graduate Certificate in CTR?
A. Yes, some students may be eligible to register for up to 2 credit hours of Mentored Research, which will count toward their Certificate electives. The Mentored Research course requires students to submit a pre-approval form before registering and a verification form at the end of the semester. Mentored Research projects must be supervised by the student's research advisor.

Q. What is the "summer intensive" term?
A. Our summer intensive term is an 8-week summer session which students can complete all required 10 credit hours of the Certificate entirely online.

Q. Do I have to complete the Graduate Certificate in CTR in one semester?
A. No, students are welcome to sign up for as few or as many classes as they can accommodate each semester. Students will remain in good standing with the university as long as they finish the program within five years.

Q. How do I set up bill payment for my employer-sponsored aid or tuition remission benefit?
A. Students whose fellowship programs or employers are paying their tuition or who are eligible for tuition remission can contact the Bursar's Office at bursar@uc.edu or visit http://www.uc.edu/bursar/paying_your_bill.html to set up a payment plan.

Q. How do I apply to graduate?
A. Students should fill out an online graduation application before the beginning of the term they want to graduate. Applications are available online at https://gradapps.uc.edu/RoadmapInt/. At the end of the term, applications will be reviewed and if approved, the Certificate will show up on the students' official UC transcripts. Students can request transcripts online at

http://www.uc.edu/registrar/record_services/transcript_ordering.html and our program offices will mail students a paper copy of their Certificate.

Q. Can I transfer credits to the CTR Training programs?

A. Yes, below is a table with details on the number of credits that can be transferred, depending on your student status:

Origin of Credits/Student Status	Max Number of Credits Transferred
Previous credits were taken at UC when student was non-matriculated	3 credits for Certificate, 12 credits for MSCTR programs **Pending Program Director approval*
Previous credits were taken at UC when student was matriculated into another program	Up to 1/3 of Certificate or MSCTR requirements (3 credits for CCTR, 10 credits for MSCTR programs) **Pending Program Director approval*
Previous credits were taken at another institution when student was non-matriculated or matriculated	Up to 1/3 of Certificate or MSCTR requirements (3 credits for Certificate, 10 credits for MSCTR programs) **Pending Program Director & Graduate School approval*

Credits earned in a degree higher than the one the student is completing at UC cannot be transferred. For example, credits taken towards an MS program cannot be applied to the Certificate and credits taken towards a PhD cannot be applied to the MSCTR programs. Students who want to continue from the Certificate and earn their MSCTR must formally apply to and be accepted into one of the MSCTR programs. Once accepted, the Certificate credits will be automatically applied toward the chosen MSCTR program.

Center for Clinical & Translational Science & Training (CCTST)

The Center for Clinical & Translational Science & Training (CCTST) was established in 2005 as the UC academic home for clinical and translational research, providing "one-stop shopping" for investigators across the AHC and beyond in need of guidance, information, support, resources and training.

The CCTST spearheaded the AHC's submission of an NIH Clinical & Translational Science Award (CTSA) application. In 2009, UC and its partner institutions CCHMC, UCMC, and Cincinnati VAMC comprised the 39th member of the CTSA Consortium, which now includes over 60 institutions. Its offices are centrally located in the CCHMC "Location S" research building, directly across the street from UC's Medical Sciences Building.

Investigators request services through the CCTST's online "Research Central" portal at http://cctst.uc.edu. The CCTST website also features service descriptions, videos, a searchable database of intramural funding opportunities, news, and a comprehensive AHC calendar of on-campus workshops, conferences and lectures of interest to clinical/translational researchers. Faculty, trainees and community/industry partners can establish free CCTST membership online, required to obtain access to consultation services through Research Central as well as special funding, training and networking opportunities. In return, members help promote CCTST goals and services, collaborate and share expertise with fellow researchers, cite CCTST assistance in publications as appropriate, and provide information for surveys and reports. To date, approximately 4,200 members have joined the CCTST, including over 400 community representatives.

CCTST Resources

With CTSA and institutional funding, the CCTST provides resources in seven major program areas, described below. Students can contact Rachael Shepler, Rachael.Shepler@cchmc.org with questions.

1) The **Pilot and Collaborative Translational and Clinical Studies (PCS Core)** expanded the highly successful CCHMC Translational Research Initiative (TRI) intramural funding program for pilot and collaborative research to the entire AHC, and increased the pool of available funds by 50%. Funding priorities for the "T1" pilot grant program are investigators new to clinical and translational research; collaborations between basic scientists and clinicians; and interdisciplinary studies, especially those involving 2 or more AHC institutions. To date, 65 T1 awards totaling over $5.7 million have been made, including 5 for FY 2016. Novel cores supporting clinical and translational research are also eligible; 4 were funded for FY 2016 (up to $50,000 each). A T1 pilot grant program for junior investigators (below the rank of associate professor) has made a total of 18 awards of up to $25,000 each in its first 5 funding rounds, through FY 2016. The Just-in-Time core funds grant program to obtain preliminary data for extramural grant applications offers 3 funding rounds annually; 27 awards of up to $7,500 were approved in calendar 2014. A matching funds program for support of clinical/translational research retreats, workshops and symposia (up to $3,000 each) accepts applications continuously. Integration of other research-related intramural grant programs with those offered by the PCS core is planned.

2) The **Biostatistics, Epidemiology and Research Design (BERD)** and **Clinical Research Ethics (CRE)** program provides all AHC investigators ready access to experts in research methods. Individualized services include review of IRB protocols; advice on study designs, including project implementation and data collection methods; guidance on appropriate statistical methods; development of data safety and monitoring plans; and consultation on clinical research ethics. Experienced CCTST research methodologists respond to CCTST members' service requests entered through the Research Central web portal within 3 business days. Since Research Central went

"live" in September 2008, over 1,000 investigators have received assistance. The core coordinates all seminars, webinars and journal clubs focused on BERD across campus, including numerous CCTST Grand Rounds and research forums annually. The BERD/CRE program also regularly offers an RFA for interdisciplinary research on ethical issues, and on research methodology in clinical and translational research (the latter added in 2010).

3) The **Biomedical Informatics (BMI)** core serves as the hub for research informatics throughout the AHC. Through close collaboration with the UC Department of Biomedical Informatics, which includes the Division of Biomedical Informatics at CCHMC and the Center for Health Informatics (CHI) at UC, a robust infrastructure is being established to improve the conduct of clinical and translational science and training. Informatics services include analysis of genomics datasets; protein informatics services such as modeling, virtual drug design, screening, and cheminformatics analysis; provision of complex datasets and data warehouse queries; and development of databases and surveys using REDCap (Research Electronic Data Capture), a software toolset and workflow methodology for small/medium research studies developed at Vanderbilt University and currently utilized across a consortium of 1,478 institutional partners in 91 countries, including over 172,000 active researchers and 235,000 projects in use or development (2015). The UC AHC has over 1,700 projects in use or development and nearly 3,000 users. With the build-out of a secure Research Network Environment (RNE) at CCHMC, credential federation with UC will allow cross-institutional access to applications like REDCap and e-PAS (IRB protocols). Current development of a SHRINE network by UC and CCHMC will enable sharing of de-identified patient data warehoused at each of the institutions, once an IRB protocol is in place. The BMI core developed a clinical and translational research informatics track in 2009 for the MS in Clinical and Translational Research program offered by the Research Education core (see #7 below). Funding from an ARRA supplement allowed 5 courses in the track to be offered online beginning in 2012.

4) The **Regulatory Knowledge & Support** program coordinates the resources of multiple initiatives centrally supported by the CCTST. The core provides institutional support and efficient and effective avenues for clinical researchers to facilitate regulatory compliance. Services include assistance with protocol development, data management, FDA filings, IRB applications and consent formulation. Regulatory Knowledge & Support also hosts discussion forums for IRB, ethical and community issues including exception from informed consent; responsible authorship; biobanking; and the use of social networking in research. In addition, the core is a regular contributor to the CCTST's monthly Grand Rounds series, including topics such as the differentiation of research and standard of care. Major core accomplishments include implementation of ClickCommerce® for IRB protocol management at UC and VAMC, which is also in use at CCHMC. This single IRB portal allows researchers to move seamlessly across the AHC, evaluate success, and refine priorities. The core has also developed and implemented CITI research ethics refresher training that is utilized and accepted across the AHC and region. UC Health's Clinical Trials Office (CTO) has begun to provide services for UC faculty, including the development of recruitment strategies and materials; study budget development; and improved contract processing. Importantly, this CTO shares leadership with that at CCHMC, building on the strengths of CCHMC's established program and ensuring continuity between institutions. Regulatory Knowledge and Support was also a founder of Collaborate to Create: Medical Devices (c2c:MD), an open forum which facilitates collaborations between faculty, students and industry partners interested in medical device development from concept to practice. With the Community Engagement core, Regulatory Knowledge & Support spearheaded the development of the Consortium of Greater Cincinnati IRBs (CGCI), a subgroup of the Greater Cincinnati Health Council focused on improving the quality of research and facilitating clinical research regionally. Together with CTSA sites in Cleveland and Columbus, the core has developed and implemented a memorandum of understanding for IRB review that allows all Ohio CTSA sites to rely on each other, and is written to allow expansion to other sites.

5) The **Clinical Translational Research Center (CTRC)** expands the former General Clinical Research Center (GCRC) based at CCHMC to provide the resources to perform high-quality, patient-oriented research at various venues across the AHC and in the community. Before September 2012, the CTRC had 12 inpatient beds, 12 outpatient rooms, and 2 treatment rooms that were shared with the Diabetes Center, staffed by 26 support personnel. Since that time, a discrete CTRC research outpatient unit adjacent to the Diabetes Center (same outpatient location) with a dedicated research nursing core, including research nurse manager, has been created; inpatient beds were substituted for "scatterbeds" (patients in beds located elsewhere at CCHMC). Five seasoned CTRC/Diabetes Center nurses have transferred to this newly created CTRC unit. This nursing core fully staffs the outpatient facility and provides nursing services for inpatient and "scatterbed" studies. Additional outpatient studies are performed in the CCHMC Oak Campus facility (approximately 6 blocks from the Medical Center) in a unit called the Cincinnati Center for Clinical Research. This facility is also the site for vaccine trials in children and adults. There is a 3000-sq.-ft. satellite center at the Cincinnati VAMC for adults and other adult patients not medically suitable for the CCHMC facility. The current facilities at UC/CCHMC provide a generous and diversified set of options for AHC investigators needing specialized research space for human studies.Core services are offered in biochemistry, body composition, behavioral science, and bionutrition. In 2014, the CTRC and affiliates supported 272 study protocols (+33%), 276 investigators from 47 specialty areas, and 25,324 hours of outpatient visits. Ninety-one journal articles published in the last year directly benefited from CTRC resources. Junior faculty and clinical fellows utilizing CTRC services are eligible to apply for a Clinical Research Feasibility Fund (CReFF) a 1-year pilot award of up to $20,000. A request for applications is offered twice annually. Two CReFF awards were made in 2014, and one in spring 2015. Clinical trial recruitment efforts are bolstered by the CCTST's participation in ResearchMatch.org, through which the AHC has enlisted more than 20 active researchers and over 300 potential research participants, many of whom have been enrolled in pediatric and adult studies. In addition, a recruitment marketing specialist working through the CCHMC and UC Health clinical trials offices is available to help investigators develop effective strategies and materials.

6) The **Community Engagement** core is broadening and strengthening collaborations between the AHC and community. Core priority areas are obesity, diabetes, asthma, infant mortality, injury, adult neuroscience, and vulnerable populations, esp. within the target communities of Avondale, Price Hill and Covington. Resources include the Community Partner Council, comprised of 39 community members, neighborhood activists and AHC members who facilitate connections through advice, education and action. Its 3 subcommittees focus on research, community training and health partnerships. Over 100 physician practices have been recruited for the Cincinnati Pediatric Research Group and other pediatric practice-based research networks (PBRNs). An adult PBRN, the Cincinnati Area Research Interest Group (CARInG) Network, has recruited 35 practices and 126 primary care providers across the region to date. Over the last 6 years, over 100 students have graduated from the Community Leaders Institute (CLI), a 6-week leadership development training program designed to enhance community research and capacity building competencies in community leaders. The 2015 CLI graduated 20 students, including community health advocates and agency representatives. CLI participants develop health-related pilot research projects and receive grants of up to $1,500 each to complete them on behalf of their community organizations over a 12 month period. Collectively, CLI grads have already leveraged their training to obtain over $3 million in new grants. A Community Engagement Speaker Series is ongoing, most recently focusing on integrating research and policy to improve health in communities. Training in community-based participatory research is offered through an online module that was revamped in 2014. To date, 44 Community Health Program Grants of up to $20,000 each have been awarded to community-academic partnerships focusing on health promotion and research in community settings such as clinics and schools. In 2014, 9 partnerships were awarded a total of over $105,000 in grants focused on core priority areas. The core has been instrumental in creating the Consortium of Greater Cincinnati IRBs (CGCI), which focuses on creating cross-institutional

collaborations and meets quarterly to discuss topics of interest such as access to the electronic health record (EHR), common informed consent language, and biobanking.

7) The **Research Education, Training & Career Development** program is intimately involved in the MS and Certificate programs in Clinical and Translational Research. Made possible by 2 ARRA supplements, an online version of the Certificate launched in summer 2011, and an online MS Informatics track was released in 2012. The Research Education program also organizes the CCTST Grand Rounds series, and offers online clinical/translational research education modules developed by the CTRC (formerly GCRC); a KL2 Research Scholars mentored career development award program, which currently supports 2 trainees; and a K23 preparation program for fellows and junior faculty which includes technical writing assistance and mock study section review. A "K Club" also meets regularly to support current and future awardees and improve their chances for obtaining independent funding, particularly R01 awards. Expanded summer research opportunities for high school and college students (14 CCTST-funded slots across 6 programs in 2014); structured clinical/translational research training for medical residents in all specialties; and a new Doctor of Nursing Practice program have also been created.

Course Descriptions

Please note the program does not have control over many of these courses, so changes may occur.

Course	Cr	Description
Advanced Biostatistics BE-7023	3	The class will cover: Multiple Linear Regression - model fitting; checking assumptions; diagnostics. Nonparametric regression - classification trees; regression trees; LOESS. Longitudinal data analysis - mixed effects models. Sample size calculations - t-test; analysis of variance; simple linear regression; logistic regression. Meta-analysis - frequentist and Bayesian analyses. Survival analysis - Kaplan-Meier and Cox regression. Survey and Questionnaire data analysis - sampling techniques; Multiple imputations - chained equations. Bayesian analysis - Monte Carlo Markov Chain simulations. **Primary Instructor:** M.B. Rao, PhD
Advanced Statistical Methods in Biomedical Research BE-8064C	2	The course examines hidden markov chains; survival analysis; meta-analysis; longitudinal studies; comparison of populations; electronic noses; medical diagnostics. **Primary Instructor:** M.B. Rao, PhD
Analysis of Internet Health Data BE-7080	3	A vast amount of data on health is available on the internet. The student will be trained how to get access to internet data following his/her line of inquiry. Once the data become accessible, the student will be trained how to analyze the data in order to answer research questions posed. The training will include usage of a computing software. One-half of the time in the course will be spent on practical demonstrations working with some specific internet health data. The remaining time will be spent working on new research projects. Once the course is complete, the student is expected to be able to download and analyze internet data on his/her own. **Primary Instructor:** M.B. Rao, PhD
Applied Survey Sampling BE-7065	3	Data collection is an integral part of any research. Conducting surveys is one vehicle of obtaining data, especially in public health. The main focus of the course is survey sampling. The following topics will be covered: Simple random sampling; Stratified random sampling; Systematic sampling; Cluster sampling; Multistage sampling; Double sampling; Network sampling; Adaptive sampling; Spatial sampling; Estimates of population features and their standard errors; Ratio estimation; Regression estimation; Implementation of sampling schemes; Sample size determination; Estimation of population size; Capture-recapture methods; Randomized response; Analysis of public health data. **Primary Instructor:** M.B. Rao, PhD

Applied Survival Analysis BE-7090C	2-3	Upon completion of the course, the student will know how to analyze lifetime data in the presence of censoring. The student will know how to compare two treatments in terms of lifetimes and will know how to take into account predictors that could influence lifetimes. The student will know how to apply knowledge of survival analysis to analyzing multiple endpoints that could arise in a clinical trial. The student will know how to analyze data using R software. Learning outcomes will be measured by homework, mid-term exam, final, and a project. **Primary Instructor:** Rhonda Szczesniak, PhD
Biostatistical & Epidemiological Consultation BE-8004/8005	1-2	Students enrolled in this course are expected to participate in projects involving the analysis of research data under the direction of a faculty member. Projects are brought to the Center for Biostatistical Services by other researchers at the College of Medicine. Presentation of results will be at the discretion of the advisor. **Primary Instructor:** Changchun Xie, PhD
Biostatistics in Research BE-7061	3	Assessment of diagnostic tests vis-a-vis gold standard procedures. Quantitative markers and ROC (Receiver Operating Characteristic) curves. One-sample and two-sample t-tests. Non-parametric analogues. One-sample and two-sample proportions. Contingency tables and chi-squared tests. Odds and odds ratios. Analysis of Variance. Kruskal-Wallis test. Confidence intervals. Multiple comparisons. Sample size calculations. R software. Descriptive statistics using R. Graphics using R. Data analysis using R. Binary logistic Regression. Model based odds ratios. Conditional logistic regression for matched case-control studies. Multinomial logistic regression. Proportional odds model. Poisson regression models. Multiple regression models and interactions. **Primary Instructor:** M.B. Rao, PhD
Clinical Research Professionals Seminar BE-9064	2	This course will provide an introduction into clinical research and the conduct of a clinical trial within the Academic Health Center. Clinical Research Professionals (CRPs) perform a large variety of tasks related to the clinical research enterprise, and this course will present an overview of duties related to a career in the field, with a focus on the practical. **Primary Instructor:** Karen King, PhD
Clinical Research Scholars Seminar BE-9066	1	This monthly seminar has four objectives: 1) to cover topics not typically covered in most courses, such as how to write papers, how to write grants, how to present research, and how to negotiate for jobs; 2) to allow students from all tracks to see and critique each others' research-in-progress presentations; 3) to enable students to meet with various cutting-edge clinical researchers; and 4) to foster further interaction among Dr. Tsevat, Dr. Grupp-Phelan, and other students in the clinical research training program. The seminar will meet monthly for 2 semesters for 1 credit. **Primary Instructors**: Lynn Babcock, MD & Jack Rubinstein, MD

Collaboration & Team Science BE-7040	2	This course provides an overview of the Science of Team Science (SciTS) for investigators who are (or will be) engaged in translational research and will be working in transdisciplinary teams. In addition to examining the theoretical and research literature on the dynamics of small groups, the course will include an examination of the construction and maintenance of highly functioning groups. Tools and exercises for assessing and improving team skills will provide hands-on experiences for learners. The course will include discussions of institutional barriers to working in teams and strategies for addressing a variety of challenges for translational researchers as they navigate their professional careers in a team-based environment. **Primary Instructor**: Jack Kues, PhD
Comparative Effectiveness Research & Patient-Centered Outcomes Research (CER/PCOR) BE-7025	2	This course examines the purpose, methods, and role of comp-arative effectiveness and patient-centered outcomes research. By leveraging the expertise of faculty across multiple institutions, this course will prepare students to develop and conduct studies involving patient and community stakeholders across a myriad of research foci. **Primary Instructors:** Katherine Bowers, PhD, MPH & Bin Huang, PhD
Computational Statistics BE-7024	3	This course is designed for students in Biostatistics and Epidemiology. The goal is to introduce computing software for data analysis purpose. The software that is primarily focused on are SAS and R. The ultimate aim is to empower the students acquire a good degree of mastery in the these software for all practical data analysis needs. The student's knowledge and expertise is tested by weekly homework assignments, a mid-term exam, a final exam, and a project. Once the course is complete, the student is expected to use these softwares almost unaided in his/her own research. The training in this course will provide the student an important and useful job skill so that he/she can compete successfully in the market place. **Primary Instructor**: Roman Jandarov, PhD
Data Analysis with R & SAS BE-8083	2	This course exemplifies the role of the computing software R and SAS in data analyses. The course will cover the basics of R, (including data structures; data manipulation; loops and functions; graphics; statistical tests; and sample size calculation), and SAS, (including importing data and different procedures). **Primary Instructor**: Liang Niu, PhD, MS
Decision Analysis & Cost-Effective Analysis BE-7068	3	This course will introduce participants to the methods and applications of analysis, cost-effectiveness analysis, and cost-benefit analysis in medical decision making. Topics will include Bayes' theorem and evaluation of diagnostic tests, the design and interpretation of decision trees, sensitivity analysis, Markov models, utility assessment, and economic analysis of healthcare programs. Examples will be drawn from both the individual patient and health policy perspectives. Students will learn decision analysis software. **Primary Instructor:** Mark Eckman, MD

Design & Management of Field Studies in Epidemiology BE-9075	3	Opportunity to acquire knowledge and skills in many aspects of the designs and conduct of field and clinical research. Includes writing a hypothesis and writing a research proposal or grant application, designing questionnaires, survey sampling, sample size determination and the art of presenting results and evaluating research. **Primary Instructors:** Kelly Brunst, PhD & Patrick Ryan, PhD
Division of Epidemiology Seminar BE-8028/8029	1	In this weekly seminar, members of the faculty and the students or outside experts present their research. **Primary Instructor:** Ranjan Deka, PhD
Epidemiology of Cancer BE-8098	2	A general overview of known associations of environmental and occupational factors with various types of cancer; includes discussion of types of studies that give rise to associations and causation. **Primary Instructor:** Susan Pinney, PhD
Epidemiology of Infectious Diseases BE-7084	2	The course covers the epidemiologic, serologic, and public health aspects of modern infectious diseases, their transmission, and methods of control. **Primary Instructor:** Florence Fulk, PhD
Epidemiology of Occupations BE-8079	2	This course offers an overview of methods and topics in occupational epidemiology. The course will focus on the concepts of epidemiologic methods as they are applied in occupational epidemiology. The course will be a mixture of lectures, directed readings, and classroom exercises that will cover epidemiologic study designs, issues of validity, measurement of exposure, ascertainment of health outcomes, approaches to analysis, and special considerations for studying the health of a working population. **Primary Instructor:** Tania Carreon-Valencia, PhD
Scientific Integrity BE-7067	1-2	This seminar discusses the ethical issues in clinical research. Course objectives are: 1) to argue the importance of integrity in research; 2) to develop effective mentoring styles; 3) to develop responsible data management and record keeping practices; 4) to discuss the ethical basis that guides research with human and animal subjects; 5) to analyze ethical authorship and publication practices; 6) to appreciate the concepts of conflict of interest, including conflict of commitment and conflict of time; and 7) to understand the concept of intellectual property and how intellectual property is protected. **Primary Instructor:** Jane Strasser, PhD

Experimental Design BE-7089	3	This course covers the statistical basis for experimental designs and the analysis of experimental data. Designs that are presented include the two-group independent and correlated design; completely randomized factorial design for more than 2 groups; nested and split plot models; repeat measure designs; complete and incomplete block designs and fractional factorial designs. Associated topics include tests for homogeneity of variance; power analysis; methods for performing multiple comparisons; fixed, random and mixed models; construction of an EMS table; and construction of proper (direct and pseudo-) F-ratios. **Primary Instructor:** Liang Niu, PhD
Introduction to Medical Informatics BE-8062	3	Medical Informatics is the multidisciplinary scientific field concerned with the acquisition, storage, retrieval, communication, and optimal use of health information for problem solving and decision-making. Health Informatics has as its driving goals the improvement of health and healthcare and the advancement of the biomedical and health sciences. Other names often used for this broad field include Health Informatics or Biomedical Informatics. This course will present graduate students with an introduction to the field of health informatics and its relation to patient care and clinical research. Specific topics will include: overview of the field, data standards; security, confidentiality, regional health information exchange, standards, terminologies, databases, data marts/data warehouses, interfaces and other topic as related to the healthcare and research setting. Learning objectives will be achieved using a variety of methods including: didactic lectures, group discussions, selected readings, demonstrations, self-study and student projects. **Primary Instructor:** Eric Hall, PhD & Brett Harnett, MS
Introduction to Biostatistics BE-7022	3	The course covers descriptive statistics, probability distributions, estimation, types of error, significance level, hypothesis tests, sample size, correlation, linear regression, non-parametric methods. **Primary Instructor:** Jun Ying, PhD
Introduction to Epidemiology BE-7076	2	The course introduces methodology for studies of disease in human populations. Topics that are covered are chronic disease, infectious disease, and occupational and environmental epidemiology. Sources, collection, handling, and interpretation of health data are also discussed. **Primary Instructors:** **Fall:** Aimin Chen, MD, PhD **Spring:** Kelly Brunst, PhD **Summer:** Jareen Meinzen-Derr, PhD
IRB Submission Process for Researchers BE-7081	1	The course provides hands-on experience with preparing a human subject research study and submitting it to the IRB, including use of the IRBs online submission site, ePAS. **Primary Instructor:** Angela Braggs-Brown, MA

Meta-Analysis BE-9061	3	Meta-analysis is the systematic quantitative review of all research studies directed toward a particular scientific or policy question. This course will cover all aspects of this process, including searching and evaluating research reports, extracting data, computing measures of effect size for continuous and categorical data, estimation of statistical models using SAS and WinBUGS software, and preparation of a manuscript. Students will conduct a meta-analysis on a topic of their choice, subject to instructor approval. **Primary Instructor:** Jeff Welge, PhD
Molecular Epidemiology BE-9073C	2	This course covers both the major theoretical concepts and practical issues involved in conducting research involving biomarkers in human populations. Class topics include: the theoretical advantages of biomarkers, criteria for evaluating potential markers, sample collection and storage, laboratory quality control considerations, issues in epidemiologic study design and analysis, ethical/legal concerns, and discussion of specific examples of research involving molecular markers of internal dose, susceptibility, early pathological alteration, and prognosis. **Primary Instructor:** Scott Langevin, PhD
Perinatal & Pediatric Epidemiology BE-7085	2	Perinatal and Pediatric Epidemiology (PPE) is a branch of epidemiology studying the risk factors that may affect human reproduction, pregnancy, birth outcomes, fetal and child development, and maternal and child health conditions. PPE utilizes surveillance, case-control study, cohort study, clinical trial, and community prevention trial to provide data regarding infertility, pregnancy loss, stillbirth, pregnancy complications, adverse birth outcomes, infant and child disorders to guide prevention efforts. The PPE course will provide an introduction to perinatal and pediatric health outcomes from a population viewpoint, describe major risk factors identified, summarize research progress and limitations, and stimulate students to identify unsolved questions and design new studies in the relevant areas. **Primary Instructor:** Aimin Chen, MD, PhD
Principles of Clinical Trials BE-7066	3	The main emphasis of the course is to address issues related to Design, Conduct, and Analysis of Clinical Trials. The topics that will be covered are: 1. The role of Institutional Review Board; 2. Protocol Development; 3. Selection of Appropriate Experimental Design; 4. Methods of Randomization; 5. Adaptive Designs; 6. Sample Size Determination; 7. Appropriate Methods of Data Analysis; 8. Interim Monitoring and When to Stop a Designed Clinical Trial; 9. Ethical Issues. The major thrust of the course is in the realm of biostatistics. A student who takes this course is expected to design a clinical trail in his/her own field including a critical review of the literature. Introduction to Biostatistics is a prerequisite for this course. **Primary Instructor:** Carl Fichtenbaum, MD

Project Management & Evaluation BE-7033	2	This course will introduce students to the foundations of carrying out clinical research projects in an academic or industry setting. Clinical Research Professionals (CRPs) perform a large variety of tasks related to the clinical research enterprise, and this course aims to give students the skills to successfully launch, carry out, conclude, and evaluate projects with a distinctly collaborative approach. Students will explore project management through practical, hands-on case studies and exercises that allow them to incorporate their own work experiences and projects into coursework. CRPs are often challenged to gain the support of people or resources not directly under their management, so tenets of team science will be incorporated throughout. **Primary Instructor:** John Gaskey, MHA
Quality Improvement & Patient Safety BE-7069	1	This course will cover the fundamentals of quality improvement and patient safety via a combination of independent reading and study, didactics and team based learning. It will focus on three main topic areas: Human error and bias, System errors and resilience and Quality Improvement and Plan-do-study-act cycles. Within and between each of these three main topic areas, students will work in teams during the class hour to apply their basic knowledge to cases. Students will also be responsible for performing and presenting a quality improvement or patient safety project during the semester. At the end of the course students will able to CRITICALLY EVALUATE and APPLY knowledge and skills from patient safety, medical error and quality improvement fields to important issues in health care, including diagnostic error, the use of checklists, testing error, medication error, surgical error, handoffs and signouts, duty hours, etc. **Primary Instructor:** Bruce Dellaposta, EdD
Regression Analysis BE-7088	3	The course covers the following topics: linear regression, least squares, multiple regression models, model diagnostics & building, correlation analysis, introductory analysis of variance and introductory logistic & Poisson regression models. **Primary Instructor:** Jun Ying, PhD
Statistical Computation & Software BE-7011	1	Statistical computation is an essential part of modern statistical analysis. Many times common statistical models or tests can be performed using codes or procedures from a statistical software package. This course is designed to introduce three commonly used statistical software packages, SAS (including SAS/STAT, SAS/BASE, and SAS Enterprise), SPSS, and R. The goal is to provide basic knowledge of these software packages to users and help them understand how to acquire, input data from digital or hard copy data sources; inspect and manipulate the data in order to meet the requirements for statistical models as well as their computational procedures; perform analyses using right codes and procedures for specific models and tests; and interpret and present findings using outputs from the computation. After taking this course, students will have better understanding of pros and cons of different software packages and know how to use them to cross validate the outputs in order to appropriate results for certain analyses. **Primary Instructor:** Jun Ying, PhD

Study Design & Analysis BE-8069	2	Students will learn to acquire knowledge and skills in selecting an optimal study design such as cohort, case-control and cross sectional and to understand and apply appropriate statistical methods for each epidemiologic design. **Primary Instructor:** Jun Ying, PhD
Successful Scientific Writing BE-8076	2	This workshop takes an active, participatory approach to help public health and health care professionals learn how to communicate the findings of their research and investigations more effectively and expedite publication of their manuscripts. Students will critique actual published and unpublished manuscripts and solve a wide range of exercises that exemplify the real-world challenges that authors face. Major components of the course include the following: basic sections of a scientific article: the purpose, elements and organization of each section, principles of style for writing in public health and epidemiology, systematic approaches to the process of writing and publishing an article in a peer review journal, and effective strategies for dealing with requests of journal editors and reviewers. **Primary Instructors:** Paul Siegel, MD, MPH (CDC) & Jen Veevers, PhD
Survey of Clinical & Translational Research I BE-9070	1	This survey introduces students to a wide variety of topics related to clinical and translational research, including professionalism, research design, review of medical literature, measurement, biostatistics, interpersonal relations and communication, and grant and manuscript preparation. **Primary Instructor:** Jackie Knapke, PhD

Other Courses in the Department or University

Students in the CTR program may find their research interests necessitate training in subject matter outside the Department of Environmental Health. Courses outside the Department can be taken for elective credit, but students must consult with their academic advisors about which classes are most appropriate. Some Departments/Divisions where students commonly find relevant electives include, but are not limited to:

Nursing (NURS)
Mathematics (MATH)
Statistics (STAT)
Educational Studies (EDST)
Graduate Medicine Interdepartmental (GNTD)
Geography (GEOG)
Molecular Genetics, Biochemistry & Microbiology (MG)
Genetic Counseling (GC)
Sociology (SOC)
Toxicology (TOX)

Courses Offered Outside the Program

Please note the program does not have control over many of these courses, so changes may occur.

Course	Cr	Description
Introduction to Data Management and Analysis with SPSS CJ-8053	1	This course provides an understanding of reading, manipulating, and analyzing data in SPSS for Windows. The logic of computer programming in SPSS is a major focus. Specific methods of data analysis include all of the statistical methods covered in the three doctoral statistics courses in addition to factor analysis, two-stage least squares, and event history (survival) analysis.
Biology of Cancer CB-8080	3	Currently, a one semester course that covers a broad spectrum of issues relating to the genesis and progression of cancer. Some topics that are covered include cell kinetics and cell cycle regulation in normal and cancerous cells, onco-genes and growth factors, tumor suppressors, the genetics of cancer, mutation and environmental exposure, signal transduction and the role of the immune system in cancer.
Business Intelligence (Data Warehousing) IS-7034 (Prerequisite: IS-7032)	2	The course introduces an emerging data management technology: data warehousing. Data warehouses have been created to integrate data from online production systems so that it can be easily accessed. The specific objectives of this class include: Understand how data warehouses differ from OLTP databases; and from client/server and distributed databases; learn dimensioning modeling using Star schema to build data warehouses; introduce the architecture and infrastructure of data warehousing; learn current applications and trends in data warehousing; and common information delivery techniques for data warehouses.

Course	Cr	Description
Statistical Principles in Clinical Research PHDD-8060	3	Regulatory, statistical and operational issues in phase I trials will be discussed. The use of first dose in humans, dose escalation schemes, determination of maximal tolerated dose, mass balance, metabolism and bioavailability will be covered along with drug-drug interaction and food-effect.
Phase I/II Clinical Trials Research and Design PHDD-8050	3	This 2nd year course covers Phase IIa studies of efficacy and short-term safety in patients and Phase IIb studies of efficacy, side effects, and clinical toxicity in controlled trials. Key elements of Phase II studies addressed are crossover, parallel studies, withdrawal, single group studies, and factorial designs. Go/no-go decision points and dose selection for phase III studies will be addressed. Other topics will include parallel formulation development and clinical supplies.
Phase III/IV Clinical Trials and Research PHDD-8070	3	This course covers both Phase IIIa and Phase IIIb studies. For Phase IIIa studies, students will learn about trials in specific subject populations and the effects of covariates such as age, gender, and disease stage. The use of surrogate end points and clinical go/no-go milestones will be discussed. Instructors will cover how one determines final formulations, doses, and indications for drugs.
Database Design IS-7032	2	The focus of this course is on data modeling and design of database systems. Entity-relationship modeling is used as the vehicle to learn conceptual modeling. Students learn techniques and procedures to map the conceptual model to its logical counterpart. The concept of normalization is stressed in the logical data model. Some exposure to relational algebra is also included. The course includes a mandatory lab component where students implement these concepts using software engineering tools (e.g. ORACLE Designer) and database management software (e.g., ACCESS, ORACLE).
Global Drug Development PHDD-601	3	Overview of research, legal regulatory and product life-cycle aspects that impact decisions in global pharmaceutical product development.
Human Genetics GC-7020	3	Introduction to basic human genetics including mitosis, meiosis, chromosome structure and mechanisms of rearrangement, inheritance, modes / mechanisms, mutational mechanism, population / quantitative genetics and biochemical genetics (polymorphisms).
Introduction to Biomedical Informatics CS-7099	3	Modeling aspects, biological motivation, problem formulation and solution as well as reference to bioinformatics tools.
Introduction to Functional Genomics GNTD-8001	3	The course will consist of a series of lectures/seminars on the theory and use of methods of functional genomics in biomedical research. Lectures will be presented by some local speakers and invited guests outside the University. The course will include four "lab" sessions offered in an electronic classroom. These sessions

Course	Cr	Description
		will provide hands-on experience application of bioinformatics principles.
Molecular and Cellular Biology GNTD-7001	3	This course is designed to give the student an opportunity to learn about new laboratory methodologies that are commonly used in epidemiology before entering their laboratory rotations. They will hear speakers discuss their laboratory technologies and the usefulness of those technologies when undertaking human research studies. This course will consist of both lecture and direct observation of the laboratory methodologies. The student will be provided with an overview of the various technologies including gene chip technologies, microarray methods, proteomics, bioinformatics and computational medicine approaches.
Advanced Java IS-8010	2	This course will serve as an introduction to web application development, using Sun's Java 2 Enterprise Edition development platform. In this regard, we will discuss technologies such as basic HTML, style sheets, Dynamic HTML, JSP, JavaBeans, JDBC, Servlets, and Java 2 programming language. It is the goal of this course to provide students with the necessary skills in designing and developing application systems with a focus on Web based application systems.
Programming for Artificial Intelligence CS-6033	3	This course will cover in detail the topics of state space search, game tree search, constraint satisfaction, logic based knowledge representation and reasoning, first order predicate calculus, uncertainty handling using bayesian probability theory, and some applications of these techniques. Applications may be selected from the area s of automated planning, natural language processing, or machine learning.
Pre-Clinical/Non-Clinical Studies for IND Approval PHDD-8030	3	Principles and regulatory guidelines for pre-clinical evaluation of the pharmacology, toxicology and pharmacokinetics of investigational drugs and biologics and key elements of the Investigational Drug (IND) application and Clinical Investigators brochures.
Development & Manufacturing of Drug Products & Medical Devices PHDD-8040	3	This course will cover ethics in clinical research; Good Clinical Practices; International Conference on Harmonization guidelines on global drug development; IRBs; informed consent; inclusion and exclusion criteria; participation of minorities, women, and children in research; HIPAA; and the differences between regulations and guidelines.

Academic Resources

How to Register for Classes

Catalyst www.catalyst.uc.edu is the UC Web site where you can register for classes, accept your aid award, pay your bill, check your grades, request a transcript, and more. The One Stop Student Service Center is located on the second floor of the University Pavilion.

Phone: 513-556-1000
Office hours: Monday - Thursday, 8-5 and Friday 9-5

Blackboard Course Management
www.canopy.uc.edu

Blackboard is extremely versatile software that not only allows instructors to easily place course materials online, but also contains multiple communication tools that allow instructors and students to collaborate in new and exciting ways, and acts as a portal to other web services at the University of Cincinnati.

The first page that is visible at log-on is called the "My UC" page. The student's courses should appear on this page in one of the boxes under the heading "My Courses." If a student's instructor is participating in Blackboard and a course appears on the student's list as "unavailable," the instructor has not yet activated the class for student viewing.

Fellowships and Scholarships

CCHMC fellows are eligible to apply for tuition funding through CCHMC's Clinical Research Fellowship program.

The Clinical Research Fellowship Program has been established to support an intensive clinical research training program for physicians interested in pursuing a research career in a subspecialty of pediatrics. The Cincinnati Children's Hospital Medical Center and Departments of Pediatrics and Environmental Health offer this two-year program from the University of Cincinnati College of Medicine.

The goal is to train research-oriented faculty in the areas of outcomes research, epidemiology, healthcare delivery and patient-oriented research for pediatric departments. The program emphasizes the conduct of independent research, mastering writing skills for grant proposals and publication and learning to present scientific data. Participants are expected to devote at least 80 percent of their time to the didactic and research portions of the curriculum. Up to 20 percent of time may be devoted to clinical care in a pediatric subspecialty.

After completion of one year of clinical training in a subspecialty, a candidate is eligible for this program.

For more information about the Clinical Research Fellowship Program, visit their website at http://www.cincinnatichildrens.org/education/clinical/fellowship/clinical-research/default/ or contact Sandy Geideman, 513-636-9776, or sandra.geideman@cchmc.org.

Graduate Student Research Forum

The Annual College of Medicine Graduate Student Research Forum is another opportunity for students to gain experience in presenting research findings. The purpose of this annual event is to promote scientific communication among students and their research advisors in our various graduate divisions, as well as to inform the scientific community about current graduate student research activities at the College of Medicine. Every graduate student should consider presenting their research poster at this forum. Monetary awards are given to the students with the most outstanding poster presentations.

Libraries

University of Cincinnati Libraries offer access to an outstanding research library collection of 2.8 million volumes and a wide range of services to help students with their research needs. Students have access to the University of Cincinnati Libraries' online library catalog and information about resources and services through these main web portals: University Libraries (www.libraries.uc.edu) or the Health Sciences Library (http://libraries.uc.edu/hsl/). The libraries' web sites serve as local gateways to OhioLINK, which includes a statewide library catalog of over 38 million items from 83 other academic libraries across Ohio as well as over 4700 electronic journals.

Each University of Cincinnati library is home to a knowledgeable staff eager to assist students, faculty, and staff with their research and service needs. Among the most important services provided by our staff are instruction in library research, assistance with the appropriate use of electronic resources, and help creating electronic Dissertations and Theses. For more information about these instruction sessions visit: http://www.libraries.uc.edu/help/th/thand.html and http://www.libraries.uc.edu/hsl/reference/edutrain.cfm. Hours of libraries vary. For information and the current semester's library hours, consult the University Libraries' web site at http://www.libraries.uc.edu/information/hours_maps/index.html

The Health Sciences Library is located on the E level of the Medical Sciences Building/CARE building. Visit the Health Sciences Library website at: http://libraries.uc.edu/hsl/. Contact information and directions follow:

Circulation Desk: 558-0127
Reference: 558-5628
Technology Support: 558-4173

The entrance to the library is in the Medical Sciences Building on the E level across from MSB E351 and between Kresge Auditorium and the bank of passenger elevators.

If you drive:

Enter the Medical Center Campus by traveling north on Eden Avenue. Just past Goodman Avenue, turn left into the Eden Avenue Garage. Park and go to the 5th floor of the garage. An elevator is located on the east side of the parking garage. The pedestrian bridge is on the 5th floor beside the elevator. Walk across the pedestrian bridge into the Academic Health Center complex.

Continue along the hall until you reach the end. Turn left and enter the Medical Sciences Building through the double doors. You are on G level. Continue on G until you reach the bank of passenger elevators on the left. Take the elevator down one floor to the E level.

The entrance to the Health Sciences Library will be just beyond the bank of elevators. Walk toward the seating area and the entrance will be on the right.

If you take the campus shuttle:

Exit the shuttle in front of the Eden Garage on Eden Avenue. Cross the street and climb the stairs to the entrance of the Center for Academic Research Excellence (CARE) building. Go through the double doors into the atrium that is between the CARE building and the Medical Sciences Building (MSB). On the left you see the HSL computer lab through the glass wall and on the right you'll see seating plus a glass "hut". Walk between the two and the entrance to the library will be on the left before you reach the bank of red brick passenger elevators on the right.

If you get dropped off in the circular drive on Albert Sabin Way:

Enter the Medical Sciences Building (MSB) and continue along the hall until you see the MSB E351 on the left and the red brick passenger elevator bank on the right. Just before the elevators, turn right and the entrance to the Health Sciences Library will be on the right just beyond the elevator bank.

Computer Account and Printing Services

The University provides all students computer accounts free of charge. The Bearcat Online system is a client-server system that allows you to exchange electronic mail (e-mail) with other computer users on campus and around the World, and access the diverse resources of the Internet. You may access your Bearcat Online account from your home, office or a campus computer lab. To request an account, go www.ucit.uc.edu/email.

Computer Printing Procedures and Charges: The College of Medicine generously subsidizes printing for its medical and graduate students. Each student printing account is given a $100 value (i.e., > 1400 B&W pages free) on July 1 of each year. Students may purchase additional printing by activating their UC ID badge as a Bearcat Campus Card and adding value to it using a personal credit card via the Bearcat Campus Card web site, or by visiting the East Campus Bookstore and adding value to card with cash, credit card, or check, or by using a Value Transfer Station on the West Campus, or calling the Bearcat Campus Card office at 556-2000.

Wireless LANS at UC: The current wireless LAN environment at UC is 802.11b and 802.11g compliant. For complete information regarding wireless data communications, please visit http://www.uc.edu/ucit/internet/oncampus/wirelessdatacommunicationswpa2.html

University Bookstores

The University of Cincinnati Bookstore is your source for all of your textbook, apparel, and supply needs. They have the largest selection of used textbooks in the community. Students need to shop early as the used books, which retail at 25% less than the new retail price, sell quickly. If you have any questions, contact them at (513) 556-1400 or www.uc.edu/bookstore.

University Health Insurance

The Mission of University Health Services is to provide superb health care and health education in a compassionate and caring environment, to assist the University in providing a safe environment for students and employees, and to provide wellness in a Just Community.

All students are required to be covered by health insurance, either the Student Insurance Program or another policy, which must be at least as comprehensive as the University policy. Full-time, co-op, and part-time students taking six or more credit hours are all eligible for coverage and will be automatically charged unless they have previously waived coverage during the current academic year. Graduate students enrolled in less than six (6) credit hours may purchase coverage with: 1) an Insurance Action Form; 2) written certification of matriculation from your academic department; and 3) payment.

Contact for U.C. Student Health Insurance Office for the latest in health care information:
www.med.uc.edu/uhs/

Mental Health Services

The UHS Mental Health Clinic provides professional, confidential mental health services for UC students with Student Health Insurance. Students can find a list of services provided on the website:
http://www.uc.edu/uhs/mental_health.html.

Services include counseling for situational stress, anxiety, depression, relationship issues, grief and loss, sexual abuse, bipolar disorders, and personality disorders. They also perform psychological assessments.

For UC students with Student Health Insurance, the cost is $17 per visit for counseling, but students should obtain an appointment referral from University Health Services first (East Campus phone number: 516-584-4457).

ID Badges / Keys

Access Control is responsible for the physical security of the University, as well as providing photo identification for all employees and students. Access Control provides the following services:

- Control and service for the over 50,000+ locks in use at the University.
- Issuance of keys to students, faculty, and staff.
- Production of photo ID badges for all University employees and students.
- Control access to areas using a card access system. This system allows access via the University photo ID card.
- http://www.uc.edu/publicsafety/Keys-Badge-Access.html
  http://keys.uc.edu/

General Information:
Badge and Key Office: 4 Edwards Center
556-4925 or 558-4998 Fax 556-4940

Parking

All students are eligible to purchase a parking decal. To park on campus one must display a Parking Services issued decal or use a parking garage and pay the hourly rate. Decals are issued on a semesterly or academic year basis and are most easily purchased through the Parking Services' web site during priority registration prior to the start of each semester. The priority registration dates coincide with those for priority class registration. Internet access for priority registration is available in the parking Offices and in some computer labs on campus. Contact the Parking Office at 556-2283 Edwards Four, or visit www.uc.edu/parking for further information.

Shuttle Bus

The University of Cincinnati offers a shuttle bus service that transports students, staff, and faculty across campus. Buses run every 7-10 minutes Monday through Friday year round (except holidays). The nearest stop to Kettering is behind Eden Garage. For information on shuttle routes and bus stops, visit their website at http://www.uc.edu/af/facilities/services/shuttle.html or call 556-4424.

Sports and Exercise

Full-time graduate students enjoy free membership to UC's Recreation Center, and part-time graduate students can join at a reduced rate. All Campus Recreation Members have access to the Campus Recreation Center on Main Campus and the Fitness Center at CARE/Crawley on the Uptown East Campus. For more information, visit: http://www.uc.edu/campusrec.html.

Dining near the Medical Center

Cincinnati offers many fine dining adventures, but few are within walking distance from the Kettering Building. If you're seeking to eat between classes, the nearest facilities are the Medical Sciences Building cafeteria, Children's Hospital Medical Center cafeteria, UCMC's cafeteria, or the Veteran's Hospital cafeteria. Chipotle and Zoup are just up the street on the corner of MLK Drive and Highland. The Kingsgate Conference Hotel also offers a buffet lunch for around $12 per person. Another venue is the University Hall cafeteria.

Campus Security
(www.uc.edu/pubsafety/)

The Department of Public Safety is comprised of four distinct, but interrelated units – University Police, Emergency Preparedness, Parking Services, and Support Services.

How to Contact the Police

Police Headquarters: 3 Edwards Center 51 West Corry Street Cincinnati, Ohio 45221
Primary contacts:

- Emergencies 911
- To contact UC Police 911 from a non-university phone or cell phone dial, 556-3911
- Non-Emergencies 556-1111, 558-1111
- Office 556-4900 (If long distance, the area code is 513)
- Email: ucpd@uc.edu

“Nightwalk”

Need an escort? Call NIGHTWALK!
Nightwalk is a volunteer service that operates from
Sunday through Thursday, from dusk until midnight.

Call 556-

Center for Clinical & Translational Science & Training

College of Medicine

Department of Environmental Health

Division of Epidemiology

www.eh.uc.edu/clinicalresearch

CCTST | Center for Clinical & Translational Science & Training