Master of Science in Clinical Epidemiology

Student Handbook

2025-2026

Center for Clinical Epidemiology and Biostatistics

Perelman School of Medicine

University of Pennsylvania

Program Contacts

Directors, MSCE		
John Farrar, MD, MSCE, PhD	816 Blockley	jfarrar@pennmedicine.upenn.edu
Tiffanie Jones, MD, MPH, MSCE	931 Blockley	tiffanie.jones@pennmedicine.upenn.edu
Associate Director, Educational Programs, CCEB		
Ebbing Lautenbach, MD, MPH, MSCE	712 Blockley	ebbing@pennmedicine.upenn.edu
Director, CCEB		
Alexis Ogdie-Beatty, MD, MSCE	1st Fl Blockley	ogdiea@pennmedicine.upenn.edu
Deputy Director, CCEB		
Sharon Xiangwen Xie, PhD	607 Blockley	sxie@pennmedicine.upenn.edu
CCEB Educational Programs Office		
Laura Orsetti	925 Blockley	laura.orsetti@pennmedicine.upenn.edu
Cindy Cassel	926 Blockley	cynthia.cassel@pennmedicine.upenn.edu
Ashley Hughes	926 Blockley	ashley.hughes@pennmedicine.upenn.edu
Kathleen Sheehy	926 Blockley	kathleen.sheehy@pennmedicine.upenn.edu
Michelle McCarthy		mccarth@pennmedicine.upenn.edu
Chair, Department of Biostatistics, Epidemiology and Informatics (DBEI)		
Enrique Schisterman, PhD	8th Fl Blockley	enrique.schisterman@pennmedicine.upenn.edu
Director, Epidemiology Division		
Sean Hennessy, PharmD, PhD	803 Blockley	hennessy@pennmedicine.upenn.edu
Director, Biostatistics Division		
Jeffrey Morris, PhD	600 Blockley	jeffrey.morris@pennmedicine.upenn.edu
Director, Informatics Division		
Marylyn Ritchie, PhD, FACMI	A301 Richards	marylyn@pennmedicine.upenn.edu

Overview of Key Dates

Date	Activity/Event
July 7, 2025	New Student Orientation
Sept. 15, 2025	Submit Annual Individual Development Plan (IDP)
Dec. 15, 2025	Submit Mini-Protocol Proposal & Mentor Approval Form
March 7-15, 2026	Spring Break (no classes)
Apr. 23-24, 2026	Protocol Presentations
May 4-6, 2025	Comprehensive Examination
Jul 1, 2026	Submit Nearly Complete Final Thesis Protocol to IRB for Approval
July 15, 2026	Submit Final Thesis Protocol & Mentor Approval Form
Aug 15, 2026	Submit IRB Approval or Exemption letter

Grants to Consider While You Are In The MSCE Program		
Grant Type and Website	**Timing**	**Description**
NIH Loan Repayment https://www.lrp.nih.gov/	September 1 to November of second year (Strongly recommended if you have loans)	NIH LRP program will pay up to $50,000 a year for two years (and sometimes a third year can be justified) towards your educational debt as long as you are spending at least 20 hours a week in active research as certified by your mentor. In general, students expand on their thesis protocol or take what they plan to submit for an F or K grant and repurpose it for this program. Almost **ALL** eligible students who apply are awarded these grants, so it is well worth the effort.
F-32 Award https://researchtraining.nih.gov/programs/fellowships/F32	December 8 April 8, August 8 of first or second year	The purpose of the Kirschstein-NRSA postdoctoral fellowship is to enhance the research training of promising postdoctoral candidates who have the potential to become productive, independent investigators in scientific health-related research fields relevant to the missions of the participating NIH Institutes and Centers. Application is usually an extension of your MSCE thesis protocol. Generally used to pay for a third year of training to allow completion of the MSCE thesis and submission of application for career development awards (NIH- K, VA, or Foundations).
K-Award (or another Career Development grant) https://researchtraining.nih.gov/programs/career-development	October 12, February 12, June 12, of second year	The K-series career development award program (usually K-23 for clinical research) is intended to provide an opportunity for early-stage investigators who need up to 5 years of protected time and additional mentored research experience to develop their independent research careers. Pays up to 75% of salaries to your university to protect your research time (about 40 hours a week). The grant can be an extension of your MSCE thesis but must propose new research. Applicants should have at least a few collaborative publications and at least one first author paper to be competitive. Having a Draft K-grant or at least well-developed Specific Aims will improve your application to Program Directors and Department Chairs at whichever institution you may wish to consider for the next step in your career.
PSOM, CHOP or departmental research grants *Website varies by department*	Varies by department	There are many small research startup grants available through the Medical School that can support costs for data, medical record review, or other activities associated with your thesis or additional projects. Please investigate this with your department and your mentor.

MASTER OF SCIENCE IN CLINICAL EPIDEMIOLOGY
CENTER FOR CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS
STUDENT HANDBOOK

INTRODUCTION

The Master of Science in Clinical Epidemiology (MSCE) program has been awarding degrees within the University of Pennsylvania Perelman School of Medicine since 1985. The program is housed in the Center for Clinical Epidemiology and Biostatistics (CCEB) in collaboration with the Department of Biostatistics, Epidemiology, and Informatics (DBEI). More than 150 faculty members contribute to the MSCE degree program. The institutional governance and oversight of the MSCE program resides in the Perelman School of Medicine (PSOM) Office of Master's and Certificate Programs (MaC) within the Office of the Vice Dean for Research and Research Training.

The primary objective of the MSCE is to launch the clinical research careers of highly motivated clinicians. Over many years the MSCE program has produced a cadre of skilled investigators trained to conduct a broad range of rigorously designed clinical research studies and prepare them for independently funded academic research careers, and to develop national leaders in academic medical and health services research. These objectives are met through the program's dedicated faculty mentorship; the focused clinical epidemiology methods and biostatistics curriculum; hands-on experience with mentored thesis development, conduct, analysis, interpretation, and publication of evidence based clinical research; and extracurricular activities (such as seminars) to broaden exposure to novel study design.

Through the MSCE program, students interact and collaborate with an extensive network of clinical researchers within the CCEB, DBEI, at Penn more broadly, and beyond. As one of the top international programs in clinical research training, the MSCE is an excellent credential for anyone desiring a career in clinical research.

MENTORSHIP

The most important component of the MSCE program is the strong commitment to mentorship and collaborative research. Each student works with their primary mentor to develop a mentorship team by selecting their biostats and third advisor to serve as their formal Thesis Committee. The MSCE Program Directors also play an active role in advising students.

Your **primary mentor** is expected to be an **epidemiologist** who provides epidemiologic guidance for all aspects of the design, conduct, analysis, and write-up of your research thesis protocol. Students are encouraged to suggest primary mentors, understanding that they are expected to have a formal epidemiology and clinical research background, and that interviewers also suggest potential candidates. Mentors are selected based on availability and areas of expertise. Primary mentors may be faculty from different subject areas, but all will have the necessary skills to work with you on the question you select for your thesis proposal. We expect that each student will have an initial meeting with their assigned primary mentor to discuss the mentoring process, what each expects, and to establish if the relationship is appropriate. On the rare occasion when the discussion raises any potential issues, these should be brought to the attention of the MSCE leadership for consideration.

It is expected that the student schedules meetings with their primary mentor once a week over the full two years of the program to receive ongoing advice across a broad range of academic, research, and career development issues. The chief role of the mentor is to provide intensive guidance throughout the thesis process, starting by refining the ideas proposed by the mentee, designing a grant format thesis protocol, conducting the thesis project, analyzing and interpreting the results, and writing the thesis report intended to become one or more publishable papers. At the start of the program, the mentor works closely with the student to design a two-year plan by discussing the sequencing of courses, suggesting electives, and the

time frame for the thesis. In addition, the mentor serves as a resource for help with all aspects of the student's didactic and self-guided learning. The mentor is also expected to help the student become involved in secondary projects —with the expectation that the student becomes a collaborator or even a primary author on additional papers— to help support the student's research career.

The **biostatistics mentor** provides statistical guidance for the thesis, helping the mentee plan for the use of their study data and the formal study driven analysis of their project. In August through September of the first year, each MSCE student is asked to consult with their primary mentor to identify a member of the CCEB biostatistics faculty to serve as their biostatistics mentor. Once the student has identified their biostatistics mentor, the student and their primary mentor should meet jointly with the biostatistics mentor (expected by October 31) to review the study design, discuss potential analysis options, and develop preliminary ideas on sample size to assess the potential feasibility of one or more proposed thesis research questions. The student should then meet with the biostatistics mentor regularly (once a month) throughout the development of the thesis, the project analysis, and the paper-writing stages. Including your primary epidemiology mentor in a joint meeting with your biostatistics mentor should occur at least once a quarter to ensure coordination of the advice you are getting. Clinical research is a collaborative enterprise, and both the research and grants are more successful when completed in collaboration with your colleagues.

A **third advisor** may be chosen by the student to provide expertise in the clinical area of study or complementary epidemiologic methodology and to serve on the Thesis Committee. This advisor can be selected from the faculty of any Department or School within the University as appropriate to meet the needs of the student. This faculty member should be selected as soon as is reasonable in discussion with and approval by the primary mentor. The third advisor often plays as large a role in the thesis design, conduct, and publication as appropriate but, at a minimum, must read, provide advice, and approve the two-page original thesis concept protocol proposal written as Specific Aims (i.e., the "mini-protocol proposal"), the full protocol in NIH grant format, and the final thesis paper. It is assumed that all members of the thesis committee will play a sufficient role in the student's project to deserve author status on any published papers.

(To learn more about the Mentor's roles for your thesis project, see the Thesis Committee section on pages 12-13.)

The MSCE Program Directors take active roles in advising all students. Drs. Farrar and Jones will meet with students at the end of the first academic year to assess progress with the program, satisfaction with the outcomes, and any issues with protocol development, plans for finding a post-training academic position, and any other items that arise.

CURRICULUM

The MSCE curriculum is designed to be completed over approximately two years. Students are required to complete 14 course units as well as several non-credit requirements. The first year consists primarily of "core" coursework and the development of a comprehensive research protocol design for the thesis. The second year includes some additional elective coursework and 2.5-4.5 course units of Master's Thesis credit. Research is an unpredictable process, and some students may require an additional course or a third year to complete their research. However, we strongly encourage the completion of coursework and the collection of data and creation of an analytic data set for the thesis project by the end of year two. ***Generally, if students follow the "standard" plan of registering for two credit units per term, they will be eligible for the August graduation period two years from their start date.***

The maximum time permitted for completion of the MSCE degree is five years from matriculation. Any

extension beyond this time limit will require a written request from the student accompanied by a detailed timeline for completion and is usually granted for only a single year. Both the student's primary mentor and the MSCE Program Leadership will need to formally review and approve the plan.

Core Courses
All students are required to successfully complete the following courses, generally taken in the first year:

- EPID 5100 - Introductory Epidemiology (1 credit) – *July to mid-August*
- EPID 5260A - Biostatistics for Epidemiologic Methods I (1 credit) – *July to mid-August*
- EPID 5260B - Biostatistics for Epidemiologic Methods I (0 credit) – *Late August to mid-October*
- EPID 5270A - Biostatistics for Epidemiologic Methods II (1 credit) – *Mid-October to December*
- EPID 5270B - Biostatistics for Epidemiologic Methods II (0 credit) – *January to March*
- EPID 5420 - Measurement of Health in Epidemiology (0.5 credit) – *September to mid-October*
- EPID 5460 - Clinical Database Research Methodology (0.5 credit) – *Mid-October to December*
- EPID 5360 - Data Management and Visualization I (0.5 credit) – *March to April*
- EPID 5370 - Data Management and Visualization II (0.5 credit) – *Late May to June*
- EPID 5600 - Issues in Research Protocol Development (0.25 credit) – *January to April*
- EPID 5700 - Critical Appraisal of the Medical Literature (0.25 credit) – *January to April*
- EPID 6400 - Advanced Topics in Epidemiology (1 credit) – *January to April*
- EPID 6100 - Tutorial in Epidemiologic Research (1 credit) – *registered in first year*

Given that the MSCE courses are specifically tailored to link the didactic teaching with the development of the epidemiologic and biostatistical skills necessary to successfully develop and complete their thesis, we generally encourage students to take all the required courses even if they have had similar courses previously. However, students may place out of Introductory Epidemiology or Biostatistics I and/or II if they have had the appropriate courses or experience and can demonstrate an adequate knowledge base to the course and MSCE directors. If students place out of a course, they will be expected to take another course appropriate for their studies to meet the 14 credit unit requirements of the degree. Students should start by discussing their plans with their primary mentor to determine the appropriateness for the exemption and then contact the CCEP Educational Programs Office to initiate the process.

Electives
The student's course of study can be tailored to individuals' needs through the appropriate selection of 2-4 electives (beyond the required courses)—that meet the requirements for the MSCE degree and satisfy grant-funding requirements. Electives can be taken in any semester they are offered starting in the spring or summer of the first year. Students should choose elective courses based on special interest areas and/or the desire for additional course work in research methods and biostatistics, or other related fields. Note that not all elective courses are offered every year, and some may be cancelled if there is insufficient interest in a year. Therefore, it is important that students develop a plan with their mentors and discuss the timing with the CCEB Educational Programs Office as they develop their thesis protocol. Students are required to document their list of proposed electives on their Individual Development Plan (IDP), which they are required to submit annually. It is understood that elective choices may change over time; students are advised to check with the CCEB Educational Programs Office to confirm scheduling. For students on training grants, an area of focus may be required including one or more electives, but in general, the decision about which courses to take should be made based on the student's interests, needs for the thesis, and future research plans. Students should discuss the range of course options for fulfilling their elective requirements for the MSCE degree with their mentor. Students may choose to focus their elective training in a specific area of interest, such as clinical trials, genetics and pharmacoepidemiology.

Independent Study
Students may choose to take one or more formal courses outside of the MSCE or as an independent study in fulfillment of their elective requirement for the MSCE degree. Independent study courses can be arranged with any Penn faculty member with the approval of the student's primary mentor and the CCEB Educational Programs Office. Before beginning any independent study, students must formally request approval in advance by submitting an "*Independent Study Request Form*" to the CCEB Educational Programs Office, prepared by the student in collaboration with the faculty member who will oversee the course of study. The form must include a brief but complete description of the proposed activity identifying: the topic to be studied; specific questions or issues to be investigated; the number of hours expected to be spent on the topic; the proposed reading list or other method of study; how the student's performance will be evaluated; and the number of course unit credits requested. Each course unit of credit for an independent study course should require approximately 150 hours of study or investigation and generally includes weekly meetings with the appropriate faculty member. The form must include a signature from the faculty member overseeing the project as well as the student's mentor. The request will be forwarded by the CCEB Educational Programs Office to the Chair of the MSCE Curriculum Committee for approval. In cases where a request is not approved, the committee will inform the student in writing. **Students MAY NOT use direct work on any aspect of their thesis research project as credit for independent study**, as this is already accounted for in the required thesis credits. However, an independent study to learn a scientific or statistical technique or epidemiologic methodology that will be important for the thesis project is acceptable and encouraged, if it is not available in a formal course. The faculty member overseeing the independent study must submit a grade to the CCEB Educational Programs Office when the student satisfactorily completes the project.

Non-Credit Academic Requirements
In addition to course work, students are required to participate in a series of non-credit programs intended to enrich their experience. These requirements include the following:

- Attendance at various **seminars** including the CCEB's Clinical Epidemiology Seminar Series, DBEI Biostatistics Seminars and/or the DBEI Seminar Series. Students are required to attend a combined total of 25 sessions throughout the duration of MSCE training. A schedule will be made available.
- Participation in the **MSCE Bioethics/RCR Training**—all students are required to obtain 8 hours of in-person training in research ethics and in the responsible conduct of research. This training is comprised of 4 sessions (2 hours each) and held annually in the fall term.
- Participation in the **MSCE Professional Development (Leadership Institute) Series**—while not required, all students are strongly encouraged to attend these interactive sessions covering topics related to how to manage a research career in the real world. These include topics such as giving presentations (especially the two-minute elevator talk), career mapping, networking, maintaining a wellness/work-life balance, and running successful research programs.
- Attendance at **MSCE grant writing lectures**—students are expected to attend three sessions in the first year of training designed to assist in the development of the thesis protocol.
- Prior to the start of any research activity, all students and faculty are required to complete the **CITI online human research training and certification program**, and all students engaging in human research must have documented, discipline-appropriate training in human research protections. Students must also complete online **HIPAA training**. Students can access and complete the training via Workday. **Please forward CITI and HIPAA certification to the CCEB Educational Programs Office**. CITI and HIPAA are required before IRB approval can be obtained.

Additionally, all students in the MSCE Program are required to obtain IRB approval **before** initiating their thesis project. As the MSCE program resides within Penn Medicine, IRB approval must be obtained from the University's Office of Regulatory Affairs (ORA). Full written IRB approval or a formal letter granting

an exemption, in compliance with all local, state, and federal laws and guidelines, is required of each separate research project, no matter where it is conducted and even if it is part of a larger and previously approved study. If data is acquired via a CHOP institutional database or collected at CHOP, the student will need to obtain the primary IRB approval through CHOP's IRB Office and then request a reciprocal approval letter from Penn's IRB. If working on an already approved project, please submit documentation that the IRB office has officially added your name as an investigator to the project. This must be completed prior to beginning any work on your research project. **The student is required to forward IRB documentation to the CCEB Educational Programs Office prior to starting work on the project and it is a requirement for graduation.**

IRB approval may require a yearly renewal and formal closure once the research and all publications are completed. Unless the thesis and published papers are completed in less than a year, a copy of your IRB renewal letter and accompanying information on the subjects recruited must be submitted to the CCEB Educational Programs Office. Closure of the IRB approval or an explanation for why it is not to be closed is a requirement for graduation. In either case, a summary table of race, sex, and ethnicity of all patients from which primary data were collected, or a description of the population used for your study, must be submitted with this report before graduation.

COMPREHENSIVE EXAMINATION

After all core requirements have been successfully completed, students are required to take the MSCE Comprehensive Examination. The purpose of the Comprehensive Examination is to ensure that candidates possess the knowledge, critical and synthetic reasoning skills, quantitative skills, and written communication skills necessary for a successful research career. Building on your full thesis protocol development you will be asked to create a full grant protocol proposal on a topic we provide over 3 days. Provided you have created your thesis protocol proposal in an appropriate NIH grant format the exam should be relatively straight forward. This skill is expected of all MSCE candidates.

Timing

The comprehensive examination will be given in May and we strongly encourage students to plan nothing else during the exam period. **Students unable to take the comprehensive examination on the announced dates must request permission from the CCEB Educational Programs Office at least one month prior to the examination dates.** Any requests after the one-month period will only be accepted if they are for unforeseen events or a family emergency. The request must be approved by the Comprehensive Examination Committee Chair and/or the Executive Education Programs Committee. If the student's request is approved a new date will be set. Our expectation is that the exam will be taken within the two-week window including the week before and the week after the officially scheduled date. Students must take the comprehensive examination within one year of completing core courses.

Eligibility

Only students who are in good academic standing may take the comprehensive examination. Any student previously placed on academic probation will be required to show evidence of remediation for the course prior to being allowed to take the exam.

Structure of the Exam

Students will be given a clinical epidemiology topic and asked to formulate a Specific Aims page (research question) and write a brief draft epidemiologic research protocol in grant format (total no more than 5 pages single-spaced, 12-point font, and 1-inch margins) to address the Specific Aims. References, tables, and diagrams are not included in the page count. There will be no single correct answer on how to design the study. Rather, students are expected to think creatively and critically, and to provide a thoughtful and compelling rationale for ALL major decisions in the design of the protocol and considering the components

of the conduct, analysis, and interpretation of the study, including at least some references when appropriate. In fact, providing a clear and compelling rationale is more important than the choices themselves. These are the same skills students are expected to acquire during the yearlong process of completing their course work and most importantly the design of their own thesis protocols. **Students will be given three working days to complete the exam.**

Grading
Each exam is graded by two faculty reviewers in a blinded fashion with the final grade decided by the Comprehensive Examination Committee. Students will receive notification via email giving a grade of 'satisfactory' or 'unsatisfactory', including the graders' comments. Students are encouraged to review their graded exam with their mentors. Due to the extensive nature of the grading process, it may take up to 6 weeks to receive results.

Students who receive a grade of 'unsatisfactory' must remediate the exam either by revising and resubmitting their work or in rare cases repeating the exam with a new study question. The plan for remediation will be determined by the Comprehensive Examination Committee and reviewed by MSCE Leadership. The student will work with the CCEB Educational Programs Office to determine a time for the exam remediation. The remediation must be completed within three months of the first exam. The comprehensive exam may only be remediated once. If the student does not pass the second time, they may no longer be eligible to receive the MSCE degree.

THE THESIS RESEARCH PROJECT

The research project is the primary focus of the MSCE training program. Each MSCE student is expected to design a research project, write a formal research protocol in NIH grant format, present the research protocol to classmates, and revise it based on their feedback. Students will then present to the CCEB faculty at the MSCE Protocol Presentations in late spring. In the early summer at the end of their first year, the student must obtain IRB approval and submit their full and final protocol in NIH grant format to the CCEB Educational Programs Office. Following submission of their full protocol, the student is expected to perform the study per protocol, analyze and interpret the results, and prepare a comprehensive scholarly scientific paper reporting the findings. If significant changes are found to be necessary to the protocol during the conduct of the research, a brief explanation of the changes and rationale should be submitted to the CCEB Educational Programs Office.

It is anticipated that the thesis will address a question of importance in the student's clinical area of interest and provide important data for future grant submissions. As such, students are encouraged to think beyond the MSCE program and plan their thesis to provide important information targeting their area of future research interest. Ideally, the thesis research project should be the first step in what we hope will be a lifetime of academic medical research. The development of the thesis research project and the written final thesis protocol should **specifically include planning for the long term and immediate next steps to advance their research objectives** to be initiated after completion of this first project. The presentation of their research protocol in an NIH format is intended to serve as a model for their future grant submissions.

Students receive 2.5-4.5 credit units for completing *EPID 9900: Master's Thesis* depending on the amount of time and effort required to complete the project. ***A suggested timeline for the thesis process is detailed below, but includes the following which must be submitted to the CCEB Educational Programs Office:***

1) mini-protocol proposal in NIH Specific Aims format,
2) a full detailed protocol in NIH grant format,
3) formal IRB approval,
4) final thesis project,
5) any resulting published papers including the PMCID number (note that this is different than the

PMID number- see below), and
6) a letter of formal closure of the IRB approval or explanation for its continuation.

The implementation of the student's research protocol is generally started during the summer of the first year. Most MSCE students complete their thesis research and write their thesis during the second year of the program making them eligible for graduation soon after the end of the program in August of the second year.

Thesis Purpose
The thesis should consolidate the student's knowledge of the principles and practice of epidemiologic research and provide them with experience in writing a comprehensive NIH grant protocol proposal. Students are personally responsible for developing their thesis, implementing their thesis project, analyzing the data collected, and summarizing the results in a publishable manuscript. Students are expected to work in close collaboration and with ongoing guidance from their thesis committee and other faculty as appropriate. The thesis provides hands-on experience in formulating one or more research questions; searching the medical literature; translating research questions into an appropriate research design; assessing study feasibility; writing a logical and detailed study protocol in NIH grant format; designing data collection instruments; conducting field work where appropriate; performing data analysis; interpreting the results and preparing a manuscript for publication. The MSCE program is designed so that each student obtains experience in each of these important facets of research. The structure of the protocol is expected to follow the NIH-R01 SF424 (R&R) format such that it could potentially be submitted for funding.

Types of Acceptable Thesis Projects
The key criterion for an acceptable thesis is that it uses a study design with a control group for comparison and be of sufficient quality and magnitude to be acceptable for publication. Feasibility and scientific merit are two major factors to consider when deliberating thesis options. In general, it should be a study that can be feasibly completed during the second year. In the past, some students have submitted grant applications for Loan Repayment or further training funds (F32) based on their protocols to obtain funding to do their thesis research, consolidating their experience in grant writing. However, since it is expected that the student will personally conduct the majority of the research, data collection, and analysis, they usually do not require funding beyond that which the student's clinical department is willing to provide. If needed, students should identify potential funding sources (often one of many Penn or CHOP research funding opportunities) with their mentors before embarking upon a study for the thesis project that is dependent on substantial funding or resource support.

The thesis project must be able to stand on its own. In particular, the study must include a control group and have a sufficient sample size to answer a research question. "Pilot" studies are generally not acceptable, but preliminary work that may lead to a larger effort in the future is encouraged, provided the work has adequate scientific merit and statistical power on its own accord. If a study is too small or not adequately designed to answer a question definitively, it will not be potentially publishable and therefore not acceptable as an MSCE thesis.

We encourage students to identify important scientific questions that need to be answered before proceeding to a definitive answer of the student's primary interest. Often these initial data collections and analysis are acceptable as theses. For example, a thesis based on an observational study of factors related to compliance with medication could precede a randomized controlled trial of methods to improve compliance. The student's primary mentor and advisors are expected to provide substantial guidance in the pursuit of an appropriate question for the thesis protocol and should be involved in every step of the process. If there are any remaining questions about the acceptability of a research question for the thesis, please do not hesitate to contact one of the Program Directors. The student is encouraged to think big by outlining a set of steps toward the answer to an important clinical issue and then developing one of the initial steps into a thesis

protocol project, while planning subsequent steps as the basis for their first grant submission.

Research questions that do not require prospective data collection are often feasible as thesis projects. Students often perform cohort or case-control studies based on chart abstraction or the use of an existing computerized patient database. Clinical decision analyses and meta-analyses, often in combination, also have been approved. Epidemiologic and biostatistical methodologic studies that are based on available data are also acceptable.

If funding is available, or the required sample size is not too large, it is possible to conduct randomized clinical trials or prospective cohort studies involving primary data collection. However, it is important to be realistic about the time and effort involved. In general, students planning to conduct a clinical trial should discuss the possible need for a third year of training with their mentors, fellowship director, and chairperson prior to embarking on this enterprise.

Starting the Thesis "From Scratch"
Students should begin the design process for their projects soon after entering the program by considering a range of options for addressing research questions of interest. The initial process is focused on finding and refining a relevant clinical question or questions suitable and appropriate to answer with a research study. Typically, these initial research ideas will require several steps to accomplish, and a substantial effort will be needed to refine the ideas into the initial step of the process. We **strongly** encourage students to learn how to present their ideas in the half to one-page Specific Aim(s) format which is an efficient method of thinking through the significance of what they would like to study and refine their research questions into an answerable hypothesis. The course work introduces the principles of research design early in the curriculum to provide the structural underpinnings of the student's discussions with their mentors. In refining the question, students often change their research focus as they realize the potential problems and possibilities available to answer questions that they find compelling. **New ideas should again be written up in a Specific Aims format as a concise way of presenting their ideas to their mentors**.

Please note that research that has been initiated prior to starting the program is generally not acceptable as an MSCE thesis. If the research questions have been defined but the protocol is not fully developed and can be modified throughout the year in response to input from the students mentoring team, it is generally acceptable as a thesis project. **The project should be of the student's own choosing**. Many students will have thought about research questions before entering the program, and continuity with prior research activities is encouraged. Important considerations are that each student takes advantage of the course work and meetings with mentor/advisors in developing the research plan, and that the thesis provides the opportunity for academic growth.

The Thesis Committee
The thesis committee consists of a minimum of three persons. The primary mentor serves as the thesis committee chair; the biostatistics mentor serves as the second member; and the third member is chosen by the student, in consultation with the primary mentor. CCEB faculty, including Senior Scholars, Associate Scholars, and Adjunct Scholars or members of the faculty from elsewhere within the University are eligible to serve as the third committee member. This is often a person with special clinical expertise in the student's area of interest.

(To learn about the selection process, see the Mentorship section on pages 5-6.),

Role of the Primary Mentor in the MSCE Thesis
The primary mentor's role is to help the student identify a feasible research question; explore alternative approaches to answering the question; refine general research ideas into Specific Aims with answerable hypotheses; identify content experts to supplement the advisor's expertise; and advise the student on

protocol development, student implementation, analysis, and summary for publication. The mentor's role is not to decide on a thesis research question for the student but, rather, the mentor should help the student translate his or her own ideas into a research project. The mentor is also responsible for ensuring that the student formulates and adheres to a timeline to complete the thesis. It is expected that the mentor's input to the research design, implementation, analysis, and writing will be sufficient to warrant being included as the senior author on the primary paper.

Role of the Biostatistics Mentor in the MSCE Thesis

Selection of the biostatistics mentor should be accomplished by the student in concert with their primary mentor by the fall of the first year. Preliminary meetings with the biostatistics mentor should: 1) further development and refining of the research question and study plan; 2) discuss and finalize the analysis plan, including estimating an appropriate sample size; 3) provide advice during the conduct of the analysis; and help in the interpretation of the results. Frequently, the initial consideration of a sample size will result in reconsidering the question and additional discussions before a reasonable study design can be achieved. For the full final protocol, a more detailed analysis plan and final sample size calculations are required, in consultation with and approval by the biostatistics mentor. Clinical research is always a collaborative effort, and it is important that the epidemiology mentor be involved in a number of meetings with the biostatistics mentor and particularly in the first meeting. The expectation is that joint meetings with the biostatistics and epidemiology mentors should occur monthly to promote collaboration.

Please note that it is the student's responsibility to conduct the statistical analyses with appropriate direction from the biostatistics mentor. The biostatistics mentor should be an active participant but should not conduct the analysis for the student. The biostatistics mentor is expected to play an important role in reviewing drafts of the MSCE protocol, thesis, and any papers submitted for publication. Typically the biostatistics mentor's contribution will be sufficient to meet most journals' requirements for authorship, and they should be included as a co-author on publications arising from the thesis work. In general, the standard position for the biostatistician in the author list is as the second author.

Also note that students are expected to work primarily with their assigned biostatistics mentors. The other biostatistics faculty, in particular the instructors for the two biostatistics courses (EPID 5260 A/B and EPID 5270 A/B) are there to help students learn the material but they would be inundated if they were asked for thesis help by all students. In addition, there is often more than one appropriate way to conduct specific analyses and students may get different advice from different faculty. This can lead to significant problems for the student and delay progress on the thesis. It is the specific role of the assigned biostatistics mentor to provide statistical advice for the thesis and to arrange additional help from other faculty if needed.

Role of the Third Thesis Committee Member in the MSCE Thesis

As early as is reasonable, but at the latest by the end of the fall semester of the first year, the student should identify a third person (in addition to the epidemiology and biostatistics mentors) who will serve on the thesis committee. This person should have expertise in the area of the project or important methodologies, and be internal to Penn (except in rare circumstances) but can come from any department or school in the University. If the student wishes to assign an external person, pre-approval is required by getting permission from their mentoring team and sending that person's CV to the CCEB Educational Programs Office with a justification for the request to allow membership to the committee.

The third committee member can have as large or small a role in the development of the project as is appropriate, but at a minimum must read and approve the mini-protocol proposal, full protocol, and final thesis. It is also expected that this person will attend the student's Protocol Presentation to the CCEB faculty at the end of the first year. If their input to the project is sufficient to meet standard criteria for authorship, it is expected that they will be included as an author. Please keep in mind that while it is often true that students seek advice from a number of people, they do not all need to be official members of their committee

for the purposes of formally reviewing their protocol and thesis.

Primary Data Collection Requirement for MSCE Students
Candidates for the MSCE degree are required to participate in a primary data collection activity. The purpose is to provide students with a meaningful experience in this critical area of research. Some examples include the development of data collection forms for studies of participant interviews or chart reviews; performing chart reviews or study participant interviews; General Clinical Research Center-based studies; and development and/or validation of an analytic dataset from existing databases (e.g., creating an analytic dataset from the raw data, but not simply creating new variables from an existing dataset). In many cases, this will occur as part of the MSCE thesis project. If it does not (usually because the thesis involves analysis of an existing analytic dataset, i.e., an existing dataset that can be analyzed without additional data collection), then the student must arrange to perform other, non-thesis work involving primary data collection and/or assembly/preparation of data under the guidance of the mentor in order to fulfill the requirements of the MSCE.

The student's mentor is responsible for helping to identify and approving an appropriate data collection activity with input from the MSCE Curriculum Committee and/or Program Directors, as needed. Ideally, these efforts will be related to the student's thesis project or will be another experience that will be supervised by the student's mentor(s). The thesis approval sent by the primary mentor must include verification that the data collection activity was appropriate. All MSCE students are required to confirm that the primary data collection requirement will be fulfilled. This confirmation is included on the student's "*Full Protocol Approval Form*," as required for the completion of *EPID 6100: Tutorial in Epidemiologic Research*.

Protocol Development
The protocol development process is one of the most important components of completing the MSCE thesis. It is an interactive process between the student and mentors that includes several phases: meetings with the mentor/advisors to think through a feasible research question and design; conducting a literature review; developing several of the ideas into Specific Aims for further discussion; finalizing one of the Specific Aims that becomes the basis for the mini-protocol proposal; writing up an initial full protocol; attending *EPID 5600: Protocol Development*; completing their finalized the protocol shortly after completing Protocol Development; obtaining IRB approval for the study; presenting the thesis protocol at the annual MSCE Protocol Presentation sessions at the end of the semester; and implementing the full protocol in the second year of the program. Students may not begin to conduct their thesis research until IRB approval has been documented and the **full written protocol has been approved by their thesis committee and submitted to the CCEB Educational Programs Office**.

Timeline for Protocol
Summer Term (first year):

- Begin weekly meetings with mentor – discuss course work/explore possible research questions for thesis
- Write up several different Specific Aims for a number of ideas for discussion with your mentors
- Conduct a comprehensive and critical literature review on likely thesis topics to assess previous work and feasibility
- Iterate until one topic is selected for development
- Refine the Specific Aims until the significance and objectives are clear, and hypotheses refined to a testable question

Fall Term (first year):

- At the beginning of September, or sooner if appropriate, begin in-depth discussions of the study

design for your Specific Aims
- Perform a systematic and critical formal literature review (if not already done) to understand what has already been published and the quality of those studies. If properly executed, this review could serve as the basis of a formal review publication.
- Draft the mini-protocol proposal through collaboration with your epidemiology and biostatistics mentors. A copy of the protocol proposal along with the completed "*Mini-Protocol Approval Form*" should be sent to the CCEB Educational Programs Office by **December 15**.
- Complete your thesis committee by identifying the third member
- Draft the full protocol using the NIH SF424 (R&R) format
  The draft protocol should be completed **prior to the start** of *EPID 5600: Protocol Development* (early January)

Spring Term (first year):
- Prepare a slide set for and present the protocol in *EPID 5600: Protocol Development*
- Refine the full protocol into a **final NIH PHS-424 format** based on feedback from discussion in EPID 5600 and input from your primary mentor and thesis committee members
- Design an appropriate database structure for your project (either data collection or data importation)
- Present at MSCE Protocol Presentations in late spring

Summer Term (second year):
- Obtain formal approval for the full final protocol (in NIH grant format) from the primary mentor and thesis committee
- Prepare the IRB submission if not done earlier and submit by **July 1**
- Submit the full final protocol in the appropriate NIH Grant PHS-424 format along with the signed "*Full Protocol Approval Form*" to the CCEB Educational Programs Office by **July 15**
- Forward IRB documentation of approval, once obtained, to the CCEB Educational Programs Office (**August**)
- Once IRB approval/exemption has been obtained, initiate the study

Fall Term (second year):
- Complete primary, secondary, or database data collection with ongoing data cleaning if needed

Spring Term (second year):
- Complete any data entry and cleaning
- Initiate protocol-driven analysis
- Initiate writing of the paper using the protocol to construct the introduction and methods with a clearly defined analysis plan.
- Plan how you want to present your data by constructing a dummy of your results tables and planning your figures which will be filled in once the data analysis is complete
- Complete writing of the paper by filling in appropriate tables, and completing your figures and results, followed by the writing of the discussion section
- If time allows, conduct further analyses for additional papers but we strongly recommend you resist the temptation to do this until after the initial paper is submitted for the degree

Summer Term (final semester)
- Submit Final Thesis and signed "*Final Thesis Approval Form*" to the CCEB Educational Programs Office prior to graduating

Mini-Protocol Proposal
The student is required to draft a mini-protocol proposal by **December 15** of the first fall term. It should consist of a single page, single spaced Specific Aims page (margins 0.5 by 0.5) outlining the rationale for your study, its potential significance to science and clinical care, and specific testable hypotheses (see below). The Specific Aims should be followed by a 1-3-page outline of the full proposal. This proposal should be approved by your thesis committee to ensure that there are no unexpected surprises in the full proposal. The mini-protocol proposal will serve as the backbone of the full protocol to follow.

The mini-protocol proposal is expected to follow the Specific Aims format of the PHS-424 form. Examples of the Specific Aims format are available in many places online and a few can be found on the program Canvas site. Generally, the Specific Aims page includes an initial paragraph consisting of the topic (1-2 sentences), the specific problem being addressed (1-2 sentences), and the **very specific purpose and significance** of the proposed research (1-2 sentences). The second paragraph provides a brief justification based scientific principals and current literature. The third paragraph outlines the methods, including source(s) of data, primary outcome, and a sentence about the primary outcome analysis. The last sentence of this paragraph should be the overall goal. This is followed by the specific aims (usually no more than two numbers AIM#1, AIM#2…) stating the goal of each Aim and a separate and specific hypothesis (Hypothesis#1, Hypothesis#2…) for that Aim, including numeric values of what is expected to be detected which can be an estimate at this stage. For example, "We hypothesize that the treated group will have a 20% greater survival than control group." Following the Aims should be a very short concluding paragraph indicating the expected outcome and the implications for science or clinical care if the results are positive **AND the implications if the results are negative**. It is recommended (but not required) that the references obtained from the systematic review be included. Verification of approval is provided by submitting the "*Mini-Protocol Approval Form***"** signed by the primary mentor, after obtaining approval from the mentoring committee.

Developing the Full Protocol
During the end of the fall semester and over the winter break, the student is expected to expand the methods outline into a draft protocol to be completed before the start of the spring semester. The NIH PHS-424 grant application format should be used, including the following sections: Specific Aims; and Research Strategy which consists of Significance, Innovation, and Approach. These sections are expansions on the information provided in the Specific Aims. Students are not expected to have a fully fleshed out protocol before the start of the Protocol Development course but to have enough in place to be able to present a reasonable structure of plans, so the section members and faculty can provide useful suggestions on how to improve the protocol.

An outline of the structure for your protocol are given below. We also recommend that you purchase the Grant Application Writer's Workbook – NIH, (most recent version) written by Grant Writers' Seminars & Workshops and is available from the website below. This manual was written in conjunction with NIH, and it contains lots of good material that can be very helpful. We recommend that you plan to read through the relevant sections as you develop your protocol.

http://www.grantcentral.com/workbooks/national-institutes-of-health/

During the spring term of the first year, in conjunction with *EPID 5600: Protocol Developm*ent, students are expected to further develop their full protocol following the NIH PHS-424 format and finalize their full thesis research project, with the final written product due **July 15**. If this is not feasible for whatever reason, students must inform the CCEB Educational Programs Office and indicate when they expect to have this completed. Students should develop this protocol with their thesis committee members. This will involve multiple reviews and iterations for refinement. The biostatistics mentor should carefully review the analysis plan and provide advice on how to best approach the data. They are NOT expected to write the analysis

plan but rather to provide the necessary advice for students to sort out the details and plan their own analysis. All committee members should be given enough time to review and comment on the protocol. Once they are all satisfied that the protocol is complete and with appropriate detail, they need to agree that the protocol can be approved. Once revisions are complete and the full protocol is approved, students should have their thesis committee sign the "*Full Protocol Approval Form*" for submission to the CCEB Educational Programs Office along with a full copy of the protocol, indicating that all members of the committee agree on the acceptance of the protocol.

The Significance section should start with a paragraph summarizing the clinical/scientific significance of the project and the remainder should then expand on the individual sentences of the first paragraph. The Approach section should describe all aspects of the study design; provide a bulleted rationale for each aspect of the design decisions; define and defend the population to be studied and source of study subjects or data; specify and justify the variables to be collected and how they will be used; method of data collection; and rationale for each particular outcome in the analysis. It also should identify the data analysis plan with specific sample size calculations and justification; and explain potential strengths and limitations of the study, specifically defining the potential effect each limitation may have on the results, and how each one will be handled. An important piece of the Approach is the feasibility justification which should be presented as the study timeline. Preliminary studies, if any, should be incorporated into the Significance section to help justify the student's study, and the Approach section to justify choice of methods to be used. Both the Significance and the Approach sections should end with a concluding paragraph restating the important features of that section.

The Innovation section between the Significance and the Approach is often an extension of the Significance and should indicate what might be novel about the study. Examples are new analysis method used on previously available data, or it could be previously available methods used on novel or not previously explored data set. It is usually only a paragraph or two. Other sections specifically pertinent to the study that should be included are a Human Subjects section justifying the use or exclusion of particular groups (i.e., older patients, children, men, women, etc.) and a brief section on potential future studies that will result from the current protocol both if the findings are positive or if they are negative. The specific PHS-424 guidelines for length (namely 1 page – Specific Aims – plus 12 pages – Research Strategy) are not an absolute requirement but it is recommended students keep the thesis protocol to less than 20 pages, references not included.

Protocol Presentation

At the end of the first year of courses, each student is required to participate in the Protocol Presentation session at which the research protocol is presented to CCEB faculty. The student's thesis committee is expected to attend the presentation and should make every attempt to be there. The format of the talk should follow the same format as the protocol described above [e.g., Specific Aims with specific Hypotheses, Significance (with Rationale for choice of the study topic), Approach (with details and a justification for each of the important components, and a careful discussion of the limitations), Discussion of the potential interpretation of both a positive and a negative result, and Future Directions (plans for next steps/ follow-up on findings)]. Each student will speak for 15 minutes with an additional 5 minutes allotted for questions and answers. Scheduling will be coordinated by the CCEB Educational Programs Office.

In order for students to learn how to better present their protocols, students are expected to work with their mentoring team in preparing the presentation and **practice the full presentation with at least one** of their mentors. While many students have given presentations before, there are many aspects of the presentation style that can be enhanced by professional reviews, critiques, and suggestions for improvement.

Conduct of the Research

It is required that the student personally conduct all aspects of the thesis protocol. In certain circumstances

where the amount of work required exceeds what could be reasonably expected of a single investigator, help can be used in the collection of data and data entry. In such cases, the student is expected to oversee the process and provide sufficient monitoring to ensure that the quality of the data is not compromised. Once the data is collected and properly entered into a computer database, the student is responsible for data cleaning, creating analytic files, and the primary analysis of the data. It is expected that the student will seek the advice of his or her mentors constantly throughout this process to ensure an efficient and appropriate study implementation and analysis process.

In addition, some students may need funding to complete their projects. While it is assumed that each student will personally perform all steps in the thesis project, there can be situations where additional funding will be needed to purchase necessary supplies, pay for laboratory testing, and, for very large studies, help with data collection. Prior to developing a thesis protocol that will require funding, the student is strongly urged to discuss potential sources with their mentors.

The Final Product

Writing up of the thesis is, again, the primary responsibility of the student, with input from the mentoring team, including reading and comments on the thesis/paper as the process progresses. The final thesis should be in the format of a journal article and should be in the general format of a paper to be submitted to a journal. The thesis can be submitted in a longer format than the final paper, but it must be acceptable and approved by the thesis committee. The primary mentor should be integrally involved in reviewing the thesis. Once the mentor's suggestions are incorporated, the thesis must be sent to the other members of the committee for review and comments. Once the student responds satisfactorily to the comments of all committee members, the thesis can be approved. Final approval of the thesis will be conveyed to the CCEB Educational Programs Office by having the committee members sign the "*Final Thesis Approval Form*" and submitting that along with a copy of the final thesis. It is not uncommon for students to submit a longer version of their write-up as their final thesis, with the actual paper submission occurring subsequently.

It is expected that the MSCE thesis will be submitted for publication and a copy of the final paper submitted to the CCEB Educational Programs Office to be included in the student's file. The MSCE program adheres to the guidelines as set forth by the University of Pennsylvania Perelman School of Medicine Authorship Policy, including qualifications for authorship, the authors and responsibilities, and disclosure of funding and potential conflicts of interests. It is expected that the student's thesis committee members will have participated in the project sufficiently to meet the requirements for authorship. Students should discuss this issue with their mentors.

NIH Public Access Policy and the PMCID Number:

In the interest of a wider availability of government funded research, **NIH now requires that the final versions** of any peer-reviewed journal articles resulting from any NIH-funded activities **must be submitted to the PubMed Central (PMC) repository**, where it will be made available to the public within 12 months after the journal article is published. ***If a PMCID number is not obtained, the publication cannot be used in any future NIH applications or reports.***

PubMed Central (PMC): PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal papers. These papers are assigned a PMCID, a series of numbers preceded by 'PMC' which is different than the PMID number automatically assigned by the NIH Medical Library. Since many MSCE students are at least partially funded by NIH money and nearly all the mentors are as well, it is expected that all published MSCE theses and any other papers published during MSCE training will acknowledge that funding in the paper and be submitted to PubMed Central. Sometimes this is done as a courtesy by the publishing journal, but **it is the responsibility of the student to ensure that it is done**. Specifics on this process is relatively straight forward and can be found at the appropriate website below:

Failure to obtain a PMCID number prevents the student from including that paper on any biosketch submitted as part of an NIH grant, and prevents the CCEB from listing the published paper in our T32 grant renewals.

PMC content is publicly accessible and integrated with other databases:
http://www.pubmedcentral.nih.gov/

About the NIH Public Access Policy: http://publicaccess.nih.gov/

The NIH Manuscript Submission System: http://www.nihms.nih.gov/

- Tutorials: https://www.nihms.nih.gov/help/tutorials/

Penn Libraries information on the Public Access Policy and Scholarly Communication:
https://guides.library.upenn.edu/oa-publishing

Questions: Contact the Biomedical Library 215-898-5818, libref@pennmedicine.upenn.edu

Procedures for Changing the Thesis
All students in the MSCE program must develop and complete a thesis project for the degree. This process involves developing a project under the guidance of the student's mentor, receiving feedback from other students and the faculty, executing the project, and writing up the thesis for approval by the thesis committee. The originally proposed thesis project will have been developed with careful guidance from the student's mentor and numerous other faculty and students. As such, the project should be tenable from both a scientific and logistic standpoint. It is only under extremely rare circumstances that a thesis project should need to be changed.

Nonetheless, it is recognized that the initially proposed thesis may become untenable due to unforeseeable circumstances. Should it become impossible to complete the originally designed thesis, a student may request to change the project. The following steps must be taken prior to changing the originally approved thesis topic:

1) The reason for not completing the originally proposed project must be documented in writing and submitted to the CCEB Educational Programs Office to be reviewed and approved by the Executive Education Programs Committee.
2) The above-mentioned faculty members must all agree that the original thesis is not viable.
3) The student must then propose an alternate thesis project. This project must meet the same requirements as the originally proposed thesis, including writing of a formal protocol under the guidance of the student's mentor (even if the project has already been started), approval of the protocol by the mentor and the thesis committee and proper execution and completion of the project. If possible, the student should present this project before the faculty.

It is recognized that students will often be working on numerous projects along with their originally proposed thesis project. One of these projects may be used as the student's thesis project **only** if the project was also developed under the guidance of the student's primary mentor. Projects developed with other faculty members, or developed prior to enrolling in the MSCE program, do not qualify as thesis projects. Regardless, all of the above-mentioned steps must be taken before the project is acceptable as a thesis.

ADMINISTRATIVE REQUIREMENTS FOR THE MSCE DEGREE

Throughout the program, students will be required to keep track of and follow through on all administrative

requirements for the MSCE degree:

- **Online Training Certification** – Students are required to complete HIPAA and CITI training and submit proof of completion.
- **Individual Development Plans (IDP)** – Every student is required to submit an annual IDP. The goal is to ensure students and mentors are communicating openly and that students are working toward developing the skills they will need to succeed. This must be submitted annually in the fall term to the CCEB Educational Programs Office.
- **Thesis Forms** – Students are required to submit a signed *Mini-Protocol Approval Form*, *Full Protocol Approval Form*, and *Final Thesis Approval Form* along with the protocols/thesis.
- **IRB Approval** – Every student must submit current IRB approval/exemption. This must be submitted prior to beginning any research on the MSCE protocol.
- **Course Evaluations** – Every student is required to complete a course and faculty evaluation for every MSCE course. These are distributed via email within the Blue evaluation system. A final grade for the course(s) will not be posted until evaluations have been submitted.
- **Mentor and Program Evaluations** – During the spring/summer each year, a mentor assessment and program survey are sent out to MSCE students. Both surveys are required components of the program.
- **Protocol Presentation** – During the spring of the student's first year, students are required to present their Protocols to the CCEB faculty and community.
- **Comprehensive Exam** – Every student must complete the Comprehensive Exam, held in May of their first year. All students must pass this exam (or satisfy appropriate remediation) in order to graduate.
- **Graduation Application** – The MSCE degree is conferred by the University of Pennsylvania Perelman School of Medicine and is granted in May, August, or December. To be considered for conferral of the degree, a student must complete a "graduation application" prior to the expected conferral date. Prior to each graduation period, the CCEB Educational Programs Office will email details and deadlines to all eligible candidates.

FELLOWSHIPS AND TUITION FUNDING

As part of our mission to train a very high caliber of clinical epidemiologists, the MSCE Program strives to secure resources that will enable us to provide as much support as possible for tuition and fees for students in the degree program. Every attempt is made to help support students accepted into the program by utilizing faculty/staff tuition benefits, supplemental tuition funding, and a limited amount of grant funding.

CCEB Fellowships

The CCEB has a limited number of NIH T32 grants to support students pursuing the two years of the MSCE training program. These fellowships may cover stipend as well as partial tuition and require a commitment of 40 hours per week to the program. Students will receive notice of the grant award prior to starting the program.

Departmental/Divisions Opportunities

Some departments have NIH T32 grants or other funds available for students. We encourage students to reach out to their departments/divisions for resources prior to joining the program.

Penn Faculty/Staff Tuition Benefits

The University offers full-time faculty, regular full-time staff, and limited-service employees tuition assistance for courses at the University of Pennsylvania. For more details on this benefit, please visit: http://www.hr.upenn.edu/pennbenefits/tuition

The IRS considers graduate tuition assistance to be taxable compensation once the benefit exceeds $5,250 in a given calendar year. Please refer to the Tuition Benefits Frequently Asked Questions (FAQ) page at: http://www.hr.upenn.edu/myhr/benefits/tuition/faq/myself#tax

Neither the MSCE program nor the CCEB can provide tax advice to students. It is strongly advised that all students using faculty/staff tuition benefits obtain tax advice from a professional accountant.

Other Funding Opportunities

In addition to the various CCEB and departmental NIH T32 grants, it is possible for students to apply for individual National Research Service Awards (NRSA). For those with educational debt, the NIH has a program for partial loan repayment for persons in clinical research (LRP): https://www.lrp.nih.gov/

In several cases it will be useful for a student's future career to apply for additional funding during training (individual NRSA grant, K grants, and foundation grants). In addition to providing critical experience in grant writing, a successful submission will demonstrate the student's fundability, provide additional time for completion of the MSCE thesis (if needed), and substantially improve competitiveness when applying for research faculty positions here and elsewhere.

In planning for a student's future in research, there are numerous potential sources of funding including governmental, foundation, and specialty groups. Governmental opportunities include National Institutes of Health (NIH) – Mentored Patient-Oriented Research Career Development Awards (K23) and NIH Pathway to Independence (PI) Awards (K99/R00). The Department of Defense (DOD) has several programs such as the Clinical Translational Research Award. Disease-oriented organizations and foundations (e.g., the American Cancer Society) are also potential sources.

Much of the necessary information is available by searching for the appropriate website. Planning for and writing an initial version of a career development award is appropriate even if students do not plan to stay at the University of Pennsylvania after training. Having the basis for a grant prepared will be an important selling point when students go for interviews and will help to demonstrate dedication to an academic research career.

Funding a Student's Research Activities

Separate from the MSCE program funding process, there are various opportunities to obtain grant support for the student's research activities through governmental, foundational, and specialty groups. Governmental awards include the NIH - Exploratory/Developmental Research Grant Award (R21) mechanism and NIH Research Project Grant Program (R01) awards, Department of Defense (DOD), Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and three tri-state departments of health. Large numbers of foundations accept grant requests, and there are a few small grant programs located at the University of Pennsylvania with revolving application dates. The website for the Office of the Vice Provost for Research and the Office of Research Support Services (ORSS) can provide information on all such grants. Students are encouraged to work closely with and utilize their mentors as a resource through grant applications.

MSCE POLICIES

In addition to specific policies listed below, the MSCE Program adheres to the broader policies set forth by the University of Pennsylvania: https://catalog.upenn.edu/pennbook/

Noteworthy MSCE policies are listed below:

Academic Grievances

Any student who has a concern about a matter related to the MSCE program, whether it is about a course, instructor, or mentorship, is encouraged to report to the CCEB Educational Programs Office to discuss. Alternatively, the student may wish to speak directly with one of the Program Directors.

Should the matter not be resolved with the aid of the Program Director, students may ask that that their request be elevated to the Associate Dean for PSOM Master's and Certificate Programs for further review. The role of the Associate Dean is to ensure that the Program has arranged for a proper review of the matter and that the evaluation was fair and impartial and in accordance with relevant University policies.

Academic Integrity

Collaborative work is vital to the spirit and intellectual life of the University. In many classes, students will be encouraged to collaborate with other students on homework, projects, or papers. The amount of collaboration will vary from class to class. It is the student's responsibility to ensure that they understand how much collaboration is permitted. The details may be clearly stated; if they are not, students should ask the instructor to be specific about how much collaboration he or she allows. Students should know where to draw the line between collaboration and what could be considered cheating.

In preparing homework assignments, students are encouraged to discuss theories and principles with classmates. However, all writing portrayed as your own must be original. Students should not copy any portion of their submitted work from reference materials or from other students. The MSCE program has a zero-tolerance policy on plagiarism. Any student caught plagiarizing will receive a grade of zero on the assignment/exam and may be referred to the Office of Student Conduct for disciplinary action.

Academic Standing

The MSCE degree program has specific academic standards that are expected of its students. Evaluation for most courses is based on letter grades as follows: "A," distinguished; "B," good; "C," unsatisfactory; "D," poor; and "F," failure. Pluses and minuses may be awarded for each letter grade, at the discretion of the course director. It is expected that all students receive a B- or better in each of the courses being applied to the MSCE degree. Any student who receives a grade lower than B- in any course (i.e., receives a C+ or lower) will be placed on academic probation. This includes students who would receive a B- in a course but instead receive an "incomplete" for any reason. A return to good academic standing is contingent on receiving an acceptable grade (B- or higher) for that course within one year. The student must make arrangements with the course director to remediate any grades lower than a B- and these arrangements must be approved by the Program Directors with input from the MSCE Curriculum Committee as needed. Options include devising a study plan and arranging with the instructor to retake or resubmit the work that led to the unacceptable grade or taking the course again during the next semester in which it is offered. Additional remediation may be required based on the judgment of the Director for the MSCE Degree Program, the student's mentor, the MSCE Curriculum Committee, and/or the course directors. Students may continue to take other courses while on probation, with the permission of the Directors for the MSCE Degree Program and course directors. Any student who receives an unacceptable grade in a course for the second time or fails to meet the remediation plan normally will be dismissed and will not be eligible for re-admission. The status of any student who is or has previously been on probation and who receives an unacceptable grade for an additional course will be reviewed by a committee that includes the MSCE Curriculum Committee, the Program Directors, and the student's mentor. This committee is authorized to dismiss the student or allow the student to remain in the program on a probationary basis.

Auditing

The MSCE program does not allow unofficial auditing of any EPID courses.

Authorship

The MSCE program adheres to the guidelines as set forth by the University of Pennsylvania Perelman School of Medicine Authorship Policy, including qualifications for authorship, the authors and

responsibilities, and disclosure of funding and potential conflicts of interests: https://www.med.upenn.edu/evdresearch/assets/user-content/documents/2_Announcement_MemoLJLRE_PerelmanSchoolofMedicineAuthorshipPolicy.pdf

Class Attendance
Our program is designed for in-person meetings between students and faculty. There is a lot of valuable and rich interaction during class that would be sub-optimal if held online. We try to schedule class times such that you have at least one (hopefully two) class-free days per week, but classes are held on campus and students are expected to come to class. Please arrange your commitments such that you can attend in person.

Code of Student Conduct
MSCE students must comply with the University's Code of Student Conduct and other University policies related to student conduct that appears in The PennBook: Resources, Policies and Procedures Handbook: https://catalog.upenn.edu/pennbook/code-of-student-conduct/
Any student who exhibits unprofessional behavior as determined by program leadership will be evaluated for probation. Continued unprofessional behavior will be grounds for removal from the program.

Continuous Registration
MSCE students are required to maintain continuous enrollment unless a formal leave of absence is granted. A leave of absence will be granted for military duty, medical reasons, or for family leave; this leave is typically for up to one year and "stops the clock" on time to completion. Personal leave for other reasons may be granted for up to one year, but it does not automatically change the time limit to complete the degree. A student who wishes to take a leave of absence must submit a written request to the CCEB Educational Programs Office for initial approval and then it will be forwarded to the Associate Dean in the Office of Master's and Certificate Programs (MAC) for final approval.

Incomplete Grades
A student who fails to complete a course within the prescribed period may receive a grade of "I" (Incomplete) at the discretion of the instructor. It is expected that students resolve an incomplete grade within one calendar year from the official end date of the course.

Parental or Medical Leave
A student who needs to take parental or medical leave during the Program should contact the Educational Programs Office to develop a plan for the duration of their leave, including working with their mentors, thesis committee, and course directors, to ensure that they have an approved plan in place prior to their time out. The student should fill out the "*MSCE Parental or Medical Leave Plan*" form as they plan their time off. If a more formal Leave of Absence is needed, the Educational Programs Office should be contacted to assist with that process.

Research Regulations Compliance
Students are required to comply with the following research regulations:
- IRB approval: All students are required to submit documentation demonstrating that IRB approval or exemption has been received for their MSCE thesis project and thereafter.
- The online CITI Certification Program
- The online HIPAA Privacy and Security Education
- Participation in the MSCE Bioethics/RCR Training

Student Disciplinary Procedures for Resolving Complaints of Sexual Assaults, Sexual Violence, Relationship Violence, and Stalking
The MSCE program abides by the University of Pennsylvania policies and procedures for resolving

complaints of sexual assaults, sexual violence, relationship violence, and stalking: https://catalog.upenn.edu/pennbook/sexual-misconduct-resource-offices-complaint-procedures/#Student_Disciplinary

Time Limit for MSCE Degree
The maximum time permitted for completion of the MSCE degree is five years from matriculation. Any extension beyond this time limit will require a written request from the student accompanied by a detailed timeline for completion. Both the student's primary mentor and the MSCE Leadership will need to formally review and approve the plan.

Transfer Credit Policy
Transfer of credit requests will be considered on an individual basis (and are rarely granted). Requests for transfer credit should be submitted to the CCEB Educational Programs Office, along with a course syllabus, for the course under consideration. The request will be formally reviewed by the MSCE Curriculum Committee. MSCE students may request to transfer a maximum of two graduate level credits from an accredited program.

PENN SYSTEMS AND STUDENT RESOURCES

Canvas
Canvas is the university's official online course management system: https://canvas.upenn.edu

Family Center at Penn
The Family Resource Center at Penn is a hub for information, resources, activities and advocacy for students and post-docs with children. https://familycenter.upenn.edu/

Graduate Student Center
The Grad Center is a hub for information, programming, resources, and support for graduate and professional students at Penn. https://gsc.upenn.edu/

Penn Card
The Penn Card is the official identification card of the University of Pennsylvania and is required for all students. The Penn Card provides access to Perelman School of Medicine (PSOM) buildings and many other university facilities. It is also used for many activities and services.
For details, visit: http://cms.business-services.upenn.edu/penncard/

PennKey
A PennKey is required to access many of the University's electronic services.
For details, visit: http://www.upenn.edu/computing/pennkey/

PennPortal
Students will access PennPortal to register for classes, view and pay bills, check grades, request transcripts etc. Be sure to bookmark this site: https://portal.apps.upenn.edu/penn_portal/portal.php

Student Health Services/ Penn Student Insurance Plan (PSIP)
http://www.vpul.upenn.edu/shs/

Weingarten Learning Resources Center
The Weingarten Learning Resources Center provides additional academic support services and programs for students at Penn. The Office of Learning Resources provides professional instruction in university relevant skills such as academic reading, writing, study strategies, and time management. Student Disability

Services provides comprehensive, professional services and programs for students who self-identify with disabilities to ensure equal academic opportunities and participation in University-sponsored programs. All services are free and confidential. https://www.vpul.upenn.edu/lrc/

Wellness at Penn
Wellness at Penn is dedicated to caring for students during their academic journey while creating a campus-wide community of care. Our team is committed to offering a wide range of opportunities to access support, clinical resources, education, and practical tools to meaningfully engage with one's health and wellbeing. https://wellness.upenn.edu/

APPENDIX I: Graduation Requirements (14 total course units/credits)

COURSE REQUIREMENTS (14 Total Course Units)		
If you follow the "standard" plan of registering for two course units per term (for seven terms), you will be eligible to graduate in August 2027.		
Core Courses: 7.5 Course Units		
EPID 5100	Introduction to Epidemiology	1
EPID 5260 A/B	Biostatistics for Epidemiologic Methods I	1
EPID 5270 A/B	Biostatistics for Epidemiologic Methods II	1
EPID 5360	Data Management and Visualization I	0.5
EPID 5370	Data Management and Visualization II	0.5
EPID 5420	Measurement of Health in Epidemiology	0.5
EPID 5460	Clinical Database Research Methodology	0.5
EPID 5600	Issues in Research Protocol Development	0.25
EPID 5700	Critical Appraisal of Epidemiologic Methods	0.25
EPID 6400	Advanced Topics in Epidemiology	1
EPID 6100	Tutorial in Epidemiologic Research	1
Electives: 2-4 Course Units		
Elective 1		
Elective 2		
Elective 3*		
Thesis Credits: 2.5-4.5 Course Units		
EPID 9900	Master's Thesis (usually spread over several semesters)	2.5-4.5

*Additional electives may be taken **in place of up to two thesis credits** provided the student's thesis is progressing on schedule and the primary mentor has approved of the plan. All students are required to complete a minimum of 2.5 CUs of *EPID 9900 Master's Thesis*.

NON-COURSE REQUIREMENTS

The following items must be completed/submitted prior to graduation. Please submit required documents to the CCEB Educational Programs Office via the MSCE Program Hub (in Canvas):

- ☐ HIPAA (September 15, 2025)
- ☐ CITI Training (September 15, 2025)
- ☐ Individual Development Plans (IDP) (September 15, 2025)
- ☐ CCEB/DBEI Seminars (25 total; held year-round)
- ☐ Ethics (RCR) Training (4 sessions/8 total hours; held in the Fall)
- ☐ Professional Development Series (Attendance is optional but strongly encouraged; held in Fall/Spring)
- ☐ Mini-Protocol and signed Approval (December 15, 2025)
- ☐ Protocol Presentations (Late April 2026)
- ☐ Comprehensive Exam (Early May 2026)
- ☐ Full Protocol and signed Approval (July 15, 2026)
- ☐ IRB Approval/Exemption (August 15, 2026)
- ☐ Final Thesis and signed Approval (August 1, 2027)

APPENDIX II: First Year Schedule

2025-2026 MSCE ACADEMIC YEAR

*Please check the **MSCE Program Hub** in Canvas for a complete list of important dates.*

Summer II 2025

See the Summer course schedule for exact dates

- Jul 7 (Mon) – *MSCE Orientation*
- Jul 7 (Mon) – *Summer II classes begin for incoming students*
- Aug 20 (Wed) – *Summer II classes end*

Fall 2025

See the Fall course schedule for exact dates

- Aug 26 (Tue) – *Fall classes begin*
- Sep 1 (Mon) – *Labor Day (no classes)*
- Sep 15 (Mon) – *HIPAA, CIT, & IDP Due*

The MSCE does not observe the Penn Fall Break in October.

- Nov 27 (Thu) - Nov 28 (Fri) – *Thanksgiving break (no classes)*
- Dec 4 (Thu) – *Fall classes end*
- Dec 15 (Mon) – *Mini-Protocol Due*

There are NO Epidemiology classes between the end of Fall term and start of Spring term.

Spring 2026

See the Spring course schedule for exact dates

- Jan 14 (Wed) – *Spring classes begin*
- Jan 19 (Mon) – *Martin Luther King Day observed (no classes)*
- Mar 9 (Mon) - Mar 13 (Fri) – *Spring break (no classes)*
- Apr 30 (Thu) – *Spring classes end*

Protocol Presentations	**Comprehensive Examination**
• April 23 (Thu) • April 24 (Fri)	• May 4 (Mon) - May 6 (Wed)

Summer I 2026

See the Summer course schedule for exact dates

- May 25 (Mon) – *Memorial Day (no classes)*
- May 26 (Tue) – *Summer I classes begin*
- Jun 19 (Thu) – *Juneteenth (no classes)*
- Jul 2 (Wed) – *Summer I classes end*

APPENDIX III: Course Descriptions

For course timing and instructors, please visit the CCEB website:
http://www.cceb.med.upenn.edu/course-descriptions

EPID 5100 – Introductory Epidemiology (1 course unit)
This course provides an introduction to the fundamentals of research in clinical epidemiology. It covers definitions of epidemiology; measures of disease frequency; measures of effect and association; epidemiologic study designs, including randomized clinical trials, cohort and case-control studies, cross-sectional surveys, and meta-analysis; and an overview of the conduct and analysis of epidemiologic studies. The course is composed of a series of 2-hour lectures and in-class lab sessions, designed to reinforce concepts introduced in the lectures.

EPID 5160 – Mathematical Models for the Control of Infectious Diseases (1 course unit)
As infectious diseases are transmitted from one host to another, the dynamics of transmission in the population of hosts follow certain basic rules. If one knows and understands these rules, one can plan rational strategies to prevent or control infections. One of the principal tools of those interested in public health interventions to control or ameliorate infectious diseases is the mathematical model. A model is just a means of representing and manipulating something that would not otherwise be accessible. This elective course provides students with the opportunity to construct models of the transmission of infectious diseases and to use these models to plan or compare disease control strategies. The course is predicated upon the notion that the act of building a mathematical model of disease transmission is often the very best way of understanding what is going on. This understanding will be further refined by the examination of more complicated and sophisticated model structures as they appear in the recent published literature.

EPID 5180 (PUBH 5170) – Geography & Public Health (1 course unit)
This course will provide an introduction to GIS in public health research and practice. Through a series of lectures and labs students will explore theories linking health and the environment, spatial analysis/epidemiology, and applications of GIS-related data collection and analysis.

EPID 5260 A/B – Biostatistics for Epidemiologic Methods I (1 course unit total)
The first half of this course will cover graphical methods, probability, discrete and continuous distributions, estimation, confidence intervals, and one-sample hypothesis testing. Emphasis is placed on understanding the proper application and interpretation of the methods. The second half of this course will cover two-sample hypothesis testing, nonparametric techniques, sample size determination, correlation, regression, analysis of variance, and analysis of covariance. Emphasis is placed on understanding the proper application and underlying assumptions of the methods presented. Laboratory sessions focus on the use of the STATA statistical package and applications to clinical data.

EPID 5270 A/B – Biostatistics for Epidemiologic Methods II (1 course unit total)
The first half of this course covers concepts in biostatistics as applied to epidemiology, primarily categorical data analysis, analysis of case-control, cross-sectional, cohort studies, and clinical trials. Topics include simple analysis of epidemiologic measures of effect; stratified analysis; confounding; interaction, the use of matching, and sample size determination. Emphasis is placed on understanding the proper application and underlying assumptions of the methods presented. Laboratory sessions focus on the use of the STATA and other statistical packages and applications to clinical data. The second half of this course covers concepts in biostatistics as applied to epidemiology, primarily multivariable models in epidemiology for analyzing case-control, cross-sectional, cohort studies, and clinical trials. Topics include logistic, conditional logistic, and Poisson regression methods; and simple survival analyses including Cox regression. Emphasis is placed on understanding the proper application and underlying assumptions of the methods presented. Laboratory sessions focus on the use of STATA and other statistical packages and applications to clinical data.

EPID 5340 – Qualitative Methods in the Study of Health, Disease and Medical Systems (1 course unit)
This course combines informal lecture and discussion with practical exercises to build specific skills for conducting qualitative research on healthcare, broadly defined. Readings include books and papers about research methodology and articles that provide exemplars and pitfalls of qualitative research. Specific topics covered include: the role of theory in qualitative research, method-research question fit, collecting different types of qualitative data (observation, interview, focus group, text, video), ethical issues in qualitative research, establishing rigor in qualitative research, introduction to qualitative data analysis using software, mixing methods, approaches for obtaining grant funding for qualitative research and writing up qualitative research studies for publication.

EPID 5360 – Data Management and Visualization I (0.5 course unit)
The objective of this two-course series is to enhance MSCE students' comfort and acumen in all aspects of clinical epidemiological data management and presentation, particularly graphical representation of results. The course progresses from best practices in data collection and database use to advanced data management, summarization of results, and data visualization, all of which are grounded in the prioritization of producing efficient and reproducible research processes. The course will cover and develop skills in: basic data collection, harmonization, and integration with Stata software; best practices for data variable derivation and creation; assessing and dealing with missing data; merging and appending datasets; management of dates and times; assessing free text data; dealing with specific data types such as ICD-9 and 10 codes, cost data, management of longitudinal and time-to-event data; production of descriptive and regression tables (for all regression types); descriptive and regression model visualization; and the use of Stata Markdown files such that research reports can be created directly from Stata. By the end of the two-course series, students will become fluent in the Stata statistical language and be uniquely positioned to advance their independent clinical epidemiological careers through best research and data presentation practices.

EPID 5370 – Data Management and Visualization II (0.5 course unit)
The objective of this two-course series is to enhance MSCE students' comfort and acumen in all aspects of clinical epidemiological data management and presentation, particularly graphical representation of results. The course progresses from best practices in data collection and database use to advanced data management, summarization of results, and data visualization, all of which are grounded in the prioritization of producing efficient and reproducible research processes. The course will cover and develop skills in: basic data collection, harmonization, and integration with Stata software; best practices for data variable derivation and creation; assessing and dealing with missing data; merging and appending datasets; management of dates and times; assessing free text data; dealing with specific data types such as ICD-9 and 10 codes, cost data, management of longitudinal and time-to-event data; production of descriptive and regression tables (for all regression types); descriptive and regression model visualization; and the use of Stata Markdown files such that research reports can be created directly from Stata. By the end of the two-course series, students will become fluent in the Stata statistical language and be uniquely positioned to advance their independent clinical epidemiological careers through best research and data presentation practices.

EPID 5420 – Measurement of Health in Epidemiology (0.5 course unit)
This course addresses the measurement of epidemiological variables, which broadly encompasses the tasks

involved in obtaining data, without which analyses cannot proceed. Course topics to be discussed include: defining the concepts of exposure, disease, and health; approaches to measuring exposures, which may be personal (i.e., psychological, behavioral, biological, or genetic) or environmental (i.e., physical, chemical, social, or organizational); approaches to measuring disease and health status; assessing the validity and reliability of measurement instruments; problems of misclassification of exposure status and disease status; missing data; instrument (e.g., questionnaire) development; and qualitative methods.

EPID 5460 – Clinical Database Research Methodology (0.5 course unit)
This course will discuss appropriate selection of healthcare databases for research questions of interest; assessment of drug exposures; validation of health outcomes of interest; and addressing biases, confounding, and missing data in databases. We will also review key aspects of research protocol development for database studies and discuss research grant applications related to these studies.

EPID 5500 – Clinical Economics and Decision Making (1 course unit)
This course focuses on the application of decision analysis and economic analysis to clinical and policy research. It provides an introduction to the general tools for decision analysis, including decision trees and Markov models, assessment of costs and patient preferences, and assessment of cost-effectiveness. Special emphasis is placed on second-order Monte Carlo analysis and its use in the construction of measures of sampling uncertainty for cost-effectiveness analysis. Seminars will include didactic material, practical exercises that include problem solving, critically analyzing published articles and learning to use computer software that facilitates decision and economic analyses.

EPID 5600 – Issues in Research Protocol Development (0.25 course unit)
This seminar focuses on major issues in research protocol development, including methodologic issues regarding different research designs, development of research questions, and plans for analysis. Each student will present his or her research protocol for open discussion during one of the seminar sessions.

EPID 5700 – Critical Appraisal of the Medical Literature (0.25 course unit)
This seminar focuses on techniques for critical appraisal of the medical literature. Each student will be responsible for at least one critical appraisal session covering different epidemiologic topics (including the evaluation of diagnostic tests, clinical course and prognosis of disease, disease etiology or causation, therapy, quality of clinical care, economic evaluation, and meta-analysis). Each week, a student will critically appraise a journal article and lead the discussion concerning that article.

EPID 5750 – Introduction to Genetic Epidemiology (1 course unit)
Recent advances have made it feasible to incorporate data on potential genetic risk factors into traditional epidemiologic studies. Hence, there is an increasing need for epidemiologists to understand the genetic basis of disease, read, and interpret genetic studies, and incorporate the collection and analysis of genetic information into studies of disease etiology. The objectives of this course are to provide epidemiologists with an understanding of: 1) basic genetics, 2) the tools used by geneticists and genetic epidemiologists, and 3) the integration of genetic data into traditional epidemiologic study designs. After completing this course, students will be able to read and interpret genetic epidemiologic studies. In addition, they will be able to design epidemiologic studies that incorporate genetic data collection and analysis.

EPID 5800 – Outcomes Research (1 course unit)
This course is divided into two main parts. The first part addresses issues related to the measurement of quality in health care. Included is a review of the classical structure-process-outcome quality paradigm. The paradigm's strengths and limitations are addressed. This part especially focuses on outcome measures of quality, and examines the validity of alternative measures. The second part deals with observational, or quasi-experimental, research studies. It addresses the advantages and limitations of alternative designs, and covers the role of clinical risk adjustment in observational studies of medical interventions. It focuses on

the problem of selection bias, and reviews recent methods for dealing with this bias, such as instrumental variables.

EPID 5840 – Health Disparities Research (1 course unit)
This course will provide an overview of research in health disparities. It will cover the historical aspects, concepts, policy, economic, genomic, and social perspectives of health disparities. It will provide students with methodological tools for health disparities research and introduce students to ongoing health disparities research by current Penn and affiliated faculty members. The course is composed of a series of weekly small group lectures and discussion, including critical appraisal of published papers, guest faculty presentations, and student presentations. Students will be expected to attend weekly meetings and participate in class discussions, prepare and lead discussions of assigned papers, review assigned readings, and draft and present a scientific protocol of their choosing related to health disparities.

EPID 6100 – Tutorial in Epidemiologic Research (1 course unit)
This is a tutorial given by each student's MSCE mentor. The mentor and student meet regularly, usually weekly. Topics include discussion and review of epidemiologic concepts and principles, guided readings in the epidemiology of a specific health area, and the development of the research protocol. Credit for this course is awarded upon completion of a research project protocol, the one to be used to fulfill the MSCE thesis requirement, which must be approved by the student's mentor. Evaluation is based on the grade received for the protocol.

EPID 6210 – Longitudinal and Clustered Data in Epidemiologic Research (1 course unit)
An introduction to the principles of and methods for longitudinal and clustered data analysis with special emphasis on clinical, epidemiologic, and public health applications. Designed for advanced MS and PhD-level students in epidemiology and related fields. Marginal and conditional methods for continuous and binary outcomes. Mixed effects and hierarchical models. Simulations for power calculations. Software will include Stata and R. Prerequisite: Completion of EPID 526 and 527 or equivalent preparation in biostatistics, including generalized linear models. Completion of semester curse in principles of epidemiology or equivalent. Good working knowledge of Stata and SAS and familiarity with principles of first-year calculus and matrix algebra. Permission of course director.

EPID 6220 – Applied Regression Models for Categorical Data (0.5 course unit)
This course will provide in-depth treatment of several topics in categorical data analysis. After a brief review of methods for contingency tables, we will introduce the idea of generalized linear models, and focus on two special cases – multiple logistic regression and log-linear models. Each topic will be presented in detail by stating the model and covering parameter estimation and interpretation, inference, model building, regression diagnostics, and assessment of model fit. Finally, we will cover extensions to both models, including models for multinomial data, analysis of matched-pair data, and random effects models. Topics will be illustrated in class with examples, and we will discuss the use of Stata to conduct the analyses.

EPID 6230 – Survival Data Analysis (0.5 course unit)
This course will focus on the specialized issues related to the analysis of survival or time-to-event data. The course begins by closely examining the features unique to survival data that distinguish these data from other more familiar types. Topics include non-parametric survival analysis methods, common survival functions, parametric survival models, the proportional hazards model, and common model-checking methods. All methods will be illustrated by in-class examples and homework sets. Prerequisite: Students should be comfortable with basic calculus concepts (e.g., derivatives, integrals, etc).

EPID 6240 – Methods in Patient-Centered Outcomes and Effectiveness Research (1 course unit)
The goal of this course is to provide a broad overview of methods used in patient centered outcomes and

effectiveness research. Expert faculty will lecture on topics such as standards for research questions, systematic reviews, patient/stakeholder engagement, causal inference, heterogeneity of treatment effect, handling missing data, data registries, pragmatic trials, diagnostic tests, health care disparities, evaluating the impact of communication interventions, and testing innovations in health care systems. Grading will largely be based on participation in class discussions.

EPID 6250 – Advanced Biostatistical Methods for Multivariable Prediction Models (1 course unit)
This course is an introduction to statistical methods that can be used to evaluate biomarker prognostic studies and multivariate prediction models. Topics will include biostatistical evaluation of biomarkers, predictive models based on various regression modeling strategies and classification trees, assessing the predictive ability of a model; internal and external validation of models; and updating prognostic models with new variables or for use in different populations. Students will learn about the statistical methods that are required by current reporting guidelines for biomarker prognostic studies or the reporting guidelines for multivariable prediction models.

EPID 6300 – Clinical Trials (1 course unit)
This course is to serve as a general introduction to clinical trials and will emphasize trial design issues. This is not a course on the biostatistics of clinical trials. It is expected that at the conclusion of the course, a student will be able to plan a clinical trial. Each class will consist of a two-hour lecture followed by a one-hour discussion. The weekly session will focus on either a group discussion of the assigned reading or a practical application based on the material presented during the two-hour lecture. Students will be evaluated on their participation in class (20%); a clinical trial document (50%), which should include the rationale for the study, study design, objectives and endpoints, sample size and analysis sections, and consent form; and a class presentation of their trial or another topic (30%).

EPID 6340 – Clinical Trial Outcomes: Measurement, Analysis, and Interpretation (1 course unit)
This course is intended to teach students the skills necessary to select and/or design appropriate outcomes for a clinical trial. Students will focus on recent changes in our understanding of clinical trial outcome measurements, analyses, and interpretation for both subjective and objective phenomena, such as adherence, use of multiple outcomes, and clinical importance. While design issues for clinical trials are the main focus, other types of clinical studies will be considered as appropriate. Students will be expected to learn about the problems inherent in the design of outcome measures of health and how to apply different epidemiologic and biostatistical concepts toward a solution. It is expected that at the conclusion of the course, students will be able to plan a clinical trial with a valid, responsive and interpretable outcome. The class will meet once weekly for a 60-minute lecture on a topic, followed by a 60- to 90-minute discussion of how that topic applies to the specific issues of interest to the students or the instructor.

EPID 6360 – Epidemiology Methods of Acute Care Research (1 course unit)
This is an advanced course addressing epidemiologic issues as they apply to important clinical topics in acute care, including emergency, hospital, and critical care medicine. Lectures and discussions will have two primary goals: 1) to explore epidemiologic methods specific to acute care settings (i.e., choice of outcomes, risk adjustment); and 2) to explore the epidemiology of particular diseases (e.g., sepsis, acute lung injury, hospital acquired infections) and research questions of current importance in these areas. This course will acquaint students with the classic literature in the field of adult and pediatric urgent care, emergency medicine, and critical care epidemiology, teach advanced epidemiologic principles using a problem-based approach, and demonstrate the strengths and weaknesses of epidemiologic research methodologies as they have been applied to acute care.

EPID 6380 – Topics in Clinical Trial Design & Analysis (1 course unit)
This course is intended to follow and be complementary to EPID 6300: Clinical Trials. It will build on the basic principles of design, conduct, and analysis introduced in that course and will go into more detail on

particular approaches. Topics covered will include noninferiority trials, phase 1 designs, multi-stage and other adaptive designs, graphical data presentations and current ethical controversies in clinical trials.

EPID 6400 – Advanced Topics in Epidemiology (1 course unit)
This course is designed to introduce students to advanced epidemiologic methods through a series of readings and discussions. The course aims to deepen the students' understanding of important concepts and controversies in contemporary epidemiology and to enhance their ability to think critically about empirical epidemiologic research. The course is intended for students who are already familiar with the fundamentals of epidemiology and biostatistics, and who wish to gain an understanding of the complex issues underlying epidemiologic study design and interpretation. Each week, one student will be responsible for leading a portion of the discussion of the assigned readings, in conjunction with a faculty member. Topics include: causal inference; study designs; use of large databases for research; predicting outcomes; and complex sampling methods.

EPID 6440 – Cardiopulmonary Epidemiology (1 course unit)
This is an advanced course that addresses epidemiologic research issues as they apply to important clinical topics in cardiovascular and pulmonary medicine. Lectures and workshops are designed to acquaint students with the classic literature in the fields of cardiovascular and pulmonary epidemiology, to use a body of literature to demonstrate the strengths and weaknesses of epidemiologic research designs as they have been applied to cardiovascular and pulmonary medicine, to expose students to the range of topics studied, to teach advanced epidemiologic principles using a problem-based approach, and to stimulate students to develop independent research questions.

EPID 6450 – Research Methods in Cancer Epidemiology (1 course unit)
Research in cancer etiology, prevention, treatment, and control includes a wide range of subject matter science, from the initial molecular changes that precede the development of cancer to issues of primary care guidelines for cancer survivors. The course reviews the possible study designs applied to cancer etiology, prevention, treatment, and control. These include randomized controlled trials and multiple types of observational studies (cohort, case-control, cross-sectional). Other topics will include causal inference, bias, and effect modification.

EPID 6460 – Reproductive Epidemiology (1 course unit)
This is an advanced course that addresses epidemiologic research issues as they apply to important clinical topics in obstetrics and gynecology and related clinical disciplines. Lectures and workshops are designed to acquaint students with important issues in the field of reproductive epidemiology, to use a body of literature to demonstrate the strengths and weaknesses of epidemiologic research designs as they have been applied to obstetrics and gynecology and related clinical disciplines, to expose students to the range of topics studied, to teach advanced epidemiologic principles using a problem-based approach, and to stimulate students interested in reproductive epidemiology to develop independent research questions.

EPID 6520 – Renal and Urologic Epidemiology (1 course unit)
The objective of this course is to prepare students to function as effective, independent researchers in the fields of renal and urologic epidemiology by providing the students an understanding of how epidemiologic research can and has advanced the knowledge of diseases in treatments of renal and urologic medicine. The structure of the course consists of a lecture series, accompanying workshops, and student presentations. The goals of the course are to acquaint students with some of the classic literature in the fields of renal and urologic epidemiology; to use a body of literature to demonstrate the strengths and weaknesses of epidemiologic research designs as they have been applied to renal and urologic medicine; to teach advanced epidemiologic principles using a problem-based approach; to expose students to the rationale of topics studied by faculty in the CCEB and the adult and pediatric nephrology and urology divisions at Penn and CHOP; and to stimulate students interested in renal and urologic epidemiology so that they may develop

independent research questions.

EPID 6560 – Epidemiologic Research Methods for Infectious Diseases (1 course unit)
This will be an advanced course addressing epidemiologic issues as they apply to important clinical topics in infectious diseases. Lectures and discussions will serve two primary goals: 1) to explore epidemiologic methods specific to infectious diseases (e.g., adherence to therapy) or that have important applications to infectious diseases (e.g., molecular epidemiology); and 2) to explore the epidemiology of particular infectious diseases or syndromes (e.g., HIV). This course will acquaint students with the classic literature in the field of infectious diseases epidemiology, teach advanced epidemiologic principles using a problem-based approach, and demonstrate the strengths and weaknesses of research methodologies as they have been applied to infectious diseases.

EPID 6580 – Gastrointestinal Epidemiology (1 course unit)
This course provides an in-depth presentation of advanced methodologic issues in conducting clinical epidemiologic research in the field of gastroenterology.

EPID 6640 – Methods in Neurologic Clinical Epidemiology (0.5 course unit)
This course will introduce students to methods and study design principles that are specific or unique to clinical research and trials in neurology, child neurology, neuro-ophthalmology, neurosurgery, and related fields.

EPID 6660 – Methods for Real-World Evidence on Therapeutics (1 course unit)
While randomized clinical trials are crucial for generating evidence about the efficacy and safety of therapeutic agents (i.e., drugs), they have limitations. Their limitations include infeasibility in certain settings, limited generalizability, and limited power to identify rare adverse effects. Real-world evidence (RWE) is evidence derived from the review and/or analysis of real-world data, which can be defined as data derived from the provision of healthcare outside of clinical trials. There is significant overlap between RWE and pharmacoepidemiology, which is the study of the health effects of drugs and other medical products in populations, and the application of this knowledge to improve health. The purpose of this course is to explore and integrate concepts essential to planning, conducting, and interpreting pharmacoepidemiologic studies to produce RWE. Methods to produce RWE are advancing rapidly. This course will provide students with: 1) a broad-based appreciation of current approaches to generating RWE; and 2) proficiency and confidence in learning and applying new pharmacoepidemiologic methods. Exemplar topics covered include: confounding control in causal inference, propensity scores, the prevalent new user design, instrumental variables, emulated trial designs, self-controlled study designs, and the use of RWE for regulatory decision making.

EPID 6720 – Biostatistical Methods to Address Confounding (1 course unit)
This course is designed to teach epidemiology students the statistical principles of analysis specific to pharmacoepidemiology study designs including the use of propensity scores, inverse probability weighting, instrumental variables and time varying covariates. Each of the twelve sessions includes both a lecture component and a laboratory component. Students will learn the statistical principles and then apply them to example study datasets. Students must participate in all sessions and must have previously completed biostatistics for epidemiologic methods I and II (EPID 5260 A/B and 5270 A/B). Laboratory sessions will be conducted on students' laptops using STATA software.

EPID 6740 – Measuring the Microbiome: Methods and Tools (1 course unit)
This is an advanced course addressing the methods and tools used to analyze microbiome data, as well as their implications for clinical study design. The course will include: (1) lectures focused on how the microbiome is measured, approaches to the analysis of highly multivariate microbiome data, and the bioinformatic tools used to execute these analyses; (2) hands-on R and command-line coding to build

familiarity with commonly used tools and analytic methods; and (3) short, practical assignments to reinforce the lectures and classwork. The course will acquaint students with classic literature in the field of microbiome research and prepare students to integrate microbiome data collection and analysis with epidemiologic research methodologies.

EPID 6750 – Advanced Methods for Analysis of Complex Genetic Traits (1 course unit)
The recent explosion in the availability of molecular level data coupled with technological advancements allowing for large-scale sequencing creates an exciting opportunity to tailor treatment decisions to the specific genetic characteristics of a patient. Epidemiologic studies will provide the tools to draw from this vast array of molecular data as well as well-established environmental risk factors to predict disease outcomes. However, understanding analytic methods for characterizing the complex interactions among genetic polymorphisms, biomarkers, environmental factors, and disease outcomes is imperative to draw meaningful and relevant conclusions from these studies. Through this course, students will understand and present advanced statistical methods and how they can be applied to the study of complex genetic traits.

EPID 7110 – Environmental Epidemiology (1 course unit)
Environmental Epidemiology is an advanced epidemiology course that addresses epidemiological research methods used to study environmental exposures from air pollution to heavy metals, and from industrial pollutants to consumer product chemicals. The course will provide an overview of major study designs in environmental epidemiology, including cohort studies, panel studies, natural experiments, randomized controlled trials, time-series, and case-crossover studies. The course will discuss disease outcomes related to environmental exposures, including cancer and diseases of cardiovascular, respiratory, urinary, reproductive, and nervous systems. Case studies in environmental epidemiology will be discussed to provide details of research methods and findings.

EPID 7140 – Grant Writing (0.5 course unit)
This course is designed to provide background and guidance on writing and submitting NIH grants. Students will submit a mini-protocol proposal at the beginning of the term. Each protocol will be reviewed by a group of 3 students from the class and scores will be given. The final project will be a full NIH protocol proposal ready for submission.

EPID 7750 – Special Topics in Genetic and Molecular Epidemiology (1 course unit)
This modular course meets the needs of students who require specialized instruction and hands-on training in specific topics that are not available in a traditional course setting. Multiple modules are available, providing advanced training in specific methods in genetic and molecular epidemiology, including the possibility of laboratory rotations to obtain hands-on laboratory experience. Each student may choose up to four modules for study during the semester-long course. Each module includes readings, meetings with faculty, problem sets, laboratory analysis, or analysis of data, as appropriate.

EPID 9900 – Master's Thesis (varies per term)
These are a series of tutorial sessions conducted by the student's mentor intended to support the student's efforts in developing a research protocol, designing a research project, and completing the study.

EPID 9999 – Independent Study in Clinical Epidemiology (up to 1 course unit)
This is a preceptorship that can be arranged with any of the CCEB faculty. The subject area and specific requirements are to be arranged as well.