

Master of Science in Clinical Epidemiology

Student Handbook

2019-2020

Center for Clinical Epidemiology and Biostatistics

Perelman School of Medicine

University of Pennsylvania



CCEB



Perelman
School of Medicine
UNIVERSITY of PENNSYLVANIA

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*MASTER OF SCIENCE IN CLINICAL EPIDEMIOLOGY
 CENTER FOR CLINICAL EPIDEMIOLOGY AND BIostatISTICS
 STUDENT HANDBOOK*

INTRODUCTION.....4

MENTORSHIP.....4

CURRICULUM5

Core Courses.....5

Electives/Independent Study5

Non-credit Academic Requirements6

COMPREHENSIVE EXAMINATION7

Timing7

Eligibility7

Structure of the Exam8

Grading.....8

THE THESIS RESEARCH PROJECT8

Thesis Purpose8

Types of Acceptable Thesis Projects9

Starting the Thesis “from scratch”9

The Thesis Committee.....10

Primary Data Collection Requirement for MSCE Students.....11

Protocol Development11

Mini-Proposal12

Developing the Full Protocol13

Protocol Presentation13

The Final Product.....14

ADMINISTRATIVE REQUIREMENTS FOR THE MSCE DEGREE.....15

FELLOWSHIPS AND TUITION FUNDING16

CCEB Fellowships16

Penn Faculty/Staff Tuition Benefits16

Other Funding Opportunities.....16

MSCE POLICIES17

MISCELLANEOUS DETAILS19

APPENDIX I: Graduation Requirements20

APPENDIX II: First Year Schedule21

APPENDIX III: Course Descriptions22

INTRODUCTION

The Master of Science in Clinical Epidemiology (MSCE) program is housed in the Clinical Epidemiology Unit (CEU) of the Center for Clinical Epidemiology and Biostatistics (CCEB). The CEU has been actively involved in clinically-oriented epidemiologic teaching and research since 1978. The MSCE degree has been awarded by the University of Pennsylvania School of Medicine since 1985. More than 150 faculty members contribute to the MSCE degree program.

The primary objectives of the MSCE are to produce a cadre of skilled investigators trained to conduct a broad range of rigorously designed clinical research studies and prepare them for 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 design of the curriculum; hands-on experience with study protocol and thesis development; and extracurricular activities such as departmental seminars.

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

MENTORSHIP

One of the most important components of the MSCE program is the strong commitment to mentorship and collaborative research. Each trainee has a mentorship team which includes an assigned primary mentor and biostatistics advisor as well as a third faculty advisor, selected with the approval of the primary mentor, to serve formally on the Thesis Committee. The MSCE Program Directors also play an active role in advising students.

It is expected that the primary mentor meets with his/her mentee at least once a week over the full two years of the program and provide ongoing advice across a broad range of career development issues. The chief role of the mentor is to provide ongoing, intensive guidance in developing the thesis concept, designing and conducting the thesis project, as well as writing the thesis report and any resulting publishable papers. At the outset of the program, the mentor works closely with the student to design his/her two-year course plan, by discussing sequencing of courses and suggesting electives. In addition, the mentor serves as a resource for ongoing 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 become a collaborator or even a primary author on additional papers--to help support the student's research career.

The biostatistics advisor serves as a mentor for the thesis project. Once the student has received notification of his/her biostatistics advisor (October), the student and the epidemiology mentor should meet with the biostatistics advisor to review the study design, develop preliminary ideas on sample size, analysis, and determine feasibility. The student should meet with the biostatistics advisor periodically (every 4-6 weeks) during the development of the thesis and again during the project analysis and paper-writing stage. Joint meetings with the biostatistics and epidemiology mentors should occur every 4-6 months to promote collaboration.

A third advisor will be chosen by the student to provide expertise in the area of study or complementary epidemiologic methodology and to serve on his or her 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 can play as large a role in the thesis design, conduct, and publication as appropriate but, at a minimum, must read and approve the two-page original thesis concept proposal (i.e., the "mini-proposal"), the full thesis proposal, and the final thesis paper.

The MSCE program directors take active roles in advising all students. Drs. Farrar and Lo Re will meet with students at the end of the first academic year to assess satisfaction with the program, progress and issues with protocol development, 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 credit units as well as several non-credit requirements. The first year consists primarily of “core” course work and the development of a comprehensive research protocol design for the thesis. The second year includes some additional elective course work and 3-5 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 recommend completion of course work and, to the extent possible, the collection of data 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 time line for completion and is usually granted for only a single year. Both the student’s primary mentor and the Executive Education Programs Committee will need to formally review and approve the plan.

Core Courses

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

- Introductory Epidemiology (EPID 510 – 1 credit) – *July to mid-August*
- Biostatistics for Epidemiologic Methods I (EPID 526 – 1 credit) – *July to mid-October*
- Biostatistics for Epidemiologic Methods II (EPID 527 – 1 credit) – *Mid-October to February*
- Measurement of Health in Epidemiology (EPID 542 – 0.5 credit) – *September to mid-October*
- Clinical Database Research Methodology (EPID 546 – 0.5 credit) – *Mid-October to December*
- Data Management for Clinical Epidemiology (EPID 532 – 0.5 credit) – *March to April*
- Issues in Research Protocol Development (EPID 560 – 0.25 credit) – *January to April*
- Critical Appraisal of the Medical Literature (EPID 570 – 0.25 credit) – *January to April*
- Advanced Topics in Epidemiology (EPID 640 – 1 credit) – *January to April*
- Tutorial in Epidemiologic Research (EPID 610 – 1 credit) – *registered in first year*

Students may place out of Introductory Epidemiology or Biostatistics I and/or II if they have had the appropriate courses or experience, with permission of the course director, and upon passing the final examination for the corresponding course. After discussing the appropriateness for exemption with his or her primary mentor, if a student wishes to pursue exemption, s/he should contact The Office of Graduate Training in Epidemiology to initiate the process.

Electives/Independent Study

The student’s course of study is designed to be tailored to their individual needs by the selection of 3-4 elective courses beyond the required first-year curriculum to meet the requirements for the MSCE degree and satisfy grant-funding requirements. 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. Students may choose to focus their elective training in a specific area of interest. The MSCE Program offers additional courses in areas such as *Bioethics, Clinical Trials, Human Genetics, Patient Centered Outcomes Research (PCOR) and Pharmacoepidemiology*. For some training grants, an area of focus may be required, but in general, the decision about which courses to take should be made based on the student’s interests and needs for their thesis and future research interests. Students should discuss the range of course options for fulfilling their elective requirements for the MSCE degree with their mentor.

Potential Areas of Focus:

Below is a listing of suggested courses for common areas of focus. In addition, it is recommended that students consider a course that addresses appropriate statistical needs and pursue a thesis relevant to the intended area of focus.

- *Bioethics*: EPID 690: Empirical Bioethics, BIOE 602: Conceptual Foundations of Bioethics; EPID 550: Clinical Economics and Decision Making.
- *Clinical Trials*: EPID 630: Clinical Trials; EPID 634: Clinical Trial Outcomes: Measurement, Analysis and Interpretation; EPID 638: Topics in Clinical Trial Design & Analysis.
- *Human Genetics*: EPID 575: Introduction to Genetic Epidemiology; EPID 675: Advanced Methods for Analysis of Complex Genetic Traits; BSTA 787: Methods for Statistical Genetics in Complex Human Disease.
- *Patient Centered Outcomes Research (PCOR)*: EPID 624: Methods in Patient Centered Outcomes and Effectiveness Research.
- *Pharmacoepidemiology*: EPID 666: Pharmacoepidemiology Research Methods; EPID 672: Biostatistical Methods to Address Confounding.

Students may choose to take one or more formal courses in fulfillment of their elective requirement for the MSCE degree. Independent study courses can also be arranged with any Penn faculty member with the approval of the student's primary mentor. Before beginning the course of independent study, students must formally request approval by submitting an "Independent Study Request Form" to the Office of Graduate Training, 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 Office of Graduate Training to the Chair of the 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 thesis credits. However, an independent study to learn a scientific or statistical technique or epidemiologic methodology that will be important for his/her 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 Office of Graduate Training 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 the CCEB's Clinical Epidemiology Seminar Series. The seminar takes place on Thursday mornings from 9-10 am, September through June. Students are required to attend a minimum of 25 sessions throughout the duration of MSCE training.
- 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 Series—all students are encouraged to attend these interactive sessions covering topics such as career mapping, networking, negotiating strategies 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 KnowledgeLink: <http://knowledgelink.upenn.edu/> **Please forward CITI and HIPAA certification to the Office of Graduate Training.** 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. **Once received, please forward IRB documentation to the Office of Graduate Training.**

IRB approval requires 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 Office of Graduate Training. 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 expected of MSCE candidates about to embark on their thesis projects.

Timing

The comprehensive examination will be given in May. Students unable to take the comprehensive examination on the announced dates must request permission from the Office of Graduate Training 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 and/or the Executive Education Programs Committee. If the student's request is approved, the dates must fall 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 research question and write a brief epidemiologic research protocol (no more than 5 pages single-spaced, 12-point font, 1-inch margins, with references, tables, and diagrams not included in the page count) to address this research question. There will be no single correct answer on how to design the study. Rather, we expect students to think creatively and critically, and to provide a thoughtful and compelling rationale for ALL major decisions in the design, 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 exactly the same skills we expect students to acquire during the yearlong process of completing their course work and designing their thesis protocols. *Students will be given two 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 'Pass' or 'Fail', 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 'fail' must remediate the exam. The plan for remediation will be determined by the Comprehensive Examination Committee and reviewed by Executive Education Programs Committee. The student will work with the Office of Graduate Training to determine a time for the exam remediation. The student will be given two weeks to complete and return the assignment. 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 are no longer 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, present the research protocol to his/her peers, and revise it based on their feedback. Students will then present their project to the CCEB faculty in late spring. Subsequently, the student must obtain IRB approval, submit the final proposal to the Office of Graduate Training, perform the study per protocol, and prepare a comprehensive scholarly scientific paper reporting the results. It is anticipated that the thesis will address a question of importance in the student's clinical area of interest. Students are encouraged to think beyond the MSCE program, and into their area of future research interest, while selecting their topic. 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 should specifically include planning for the long term and immediate next steps that will be initiated after completion of this first project.

Students receive 3-5 credit units for completing the Master's Thesis (EPID 900). *A suggested timeline for the thesis process is detailed below, but includes the following, all of which must be submitted to the Office of Graduate Training: 1) mini-proposal, 2) a full detailed proposal, 3) formal IRB approval, 4) final thesis project, 5) any resulting published papers including the PMID number (note that this is different than the PMID number), and 6) a letter of formal closure of the IRB approval or explanation for its continuation.* The implementation of the student's research proposal 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.

Thesis Purpose

The thesis should consolidate the student's knowledge of the principles and practice of epidemiologic research, and provide their first experience in writing a comprehensive NIH grant-style proposal. Students are expected to personally develop their theses, implement their thesis project, analyze the data collected, and summarize the results in a publishable manuscript in collaboration with 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; designing data collection instruments; conducting field work where

appropriate; performing data analysis; and preparing a manuscript for publication. The MSCE program requires that a student obtain experience in each of these facets of research. The structure of the proposal is expected to follow the [NIH-R01 PHS-424 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 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 possible to complete the study during the second year. In the past, some students have submitted grant applications based on their proposals 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, there are often ways to conduct a study without funding beyond that which the student's clinical department is willing to provide. Students generally 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 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. However, in many cases, there are important scientific questions to be answered before conducting a major study. Often these are acceptable as theses. 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 proposal and should be involved in every step of the process. The student is encouraged to think big by outlining a set of steps toward the answer to an important clinical issue and to then develop one of the initial steps into a thesis project and proposal, 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. A number of students have performed 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 that will be translated into the Specific Aim(s) of the thesis project. The course work introduces the principles of research design early in the curriculum to provide the structural underpinnings of the students' 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.

Please note that research that has been initiated prior to starting the program will not be 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 all of the resources available to the student in the CCEB, it is

likely that an acceptable project can be designed. The project should be of the student's own choosing and related to his/her clinical interests. Many students will have thought about research questions before entering the program, and continuity with prior research activities is expected and 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 advisor 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. S/he is often a person with special clinical expertise in the student's area of interest.

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; 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 assign a thesis to 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 inclusion as the senior author on the primary paper.

Role of the Biostatistics Advisor in the MSCE Thesis

Preliminary meetings with the biostatistics advisor should be aimed at refining the study plan, discussing and finalizing the analysis plan, and estimating a sample size. 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 proposal, a more detailed analysis plan and final sample size calculations should be completed, in consultation with the biostatistics advisor. It is important that the epidemiology mentor be involved in the first meeting. Joint meetings with the biostatistics and epidemiology mentors should occur every 4-6 months to promote collaboration.

Please note that following data collection, it is the student's responsibility to conduct the statistical analyses, again with appropriate direction from the biostatistics advisor. The biostatistics advisor should be an active participant but should not implement the analysis plan for the student. He/she is expected to play an important role in reviewing drafts of the MSCE protocol, thesis, and any papers submitted for publication. It is typically the case that the biostatistics advisor's contribution will be sufficient to meet most journals' requirements for authorship, and s/he should be included as a co-author on publications arising from the thesis work.

Also note that students are expected to work primarily with their assigned biostatistics advisors. The other biostatistics faculty, in particular the instructors for the two Biostatistics courses EPID 526 and EPID 527 who the student will get to know well, would be inundated if they were asked for thesis help by all of their students. Because of weekly contact in the classroom, these two instructors will be extremely busy answering questions concerning the material being taught and cannot realistically take on the additional work of providing guidance to students on their proposals. 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 his/her progress on the thesis. It is the specific role of the assigned biostatistics advisors to provide statistical advice for the thesis and to arrange additional help if needed.

Role of the Third Thesis Committee Member

As early as is reasonable, but at the latest before their final proposal is submitted, the student should identify a third person (in addition to the epidemiology mentor and biostatistics advisor) who will serve on the thesis committee. This person should have expertise in the area of the project 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 to his/her committee, pre-approval is required by sending that person's CV to the Office of Graduate Training with a justification for the request to allow membership to the committee. This 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-proposal, full proposal, and final thesis. It is also expected that this person will attend the students' project presentations to the CCEB faculty at the end of the 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 Curriculum Committee and/or Director of the MSCE program, 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 research proposal approval form, as required for the completion of EPID 610: 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 his/her mentor/advisors 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-proposal; writing up an initial full protocol; attending EPID 560: Protocol Development; finalizing the proposal and 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. 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 Office of Graduate Training.

Timeline for Protocol

Summer Term (first year):

- Begin weekly meetings with mentor--discuss course work/explore possible research questions for thesis
- Conduct a literature review on likely thesis topics
- Write up Specific Aims for discussion
- Iterate until one topic is selected for development
- Refine objectives and specific aims

Fall Term (first year):

- At the beginning of September, or sooner if appropriate, begin in-depth discussions of the study design.
- Perform a systematic formal literature review (if not already done) to understand what has already been published. If properly executed, this review could serve as the basis of a formal review publication.
- Draft the mini-proposal through collaboration with your epidemiology mentor and biostatistics advisor. A copy of the proposal along with the completed “Mini-Proposal Form” should be sent to the Office of Graduate Training by *mid-November*.
- Form a thesis committee by identifying the third member
- Draft the full proposal using the [NIH PHS-424 format](#)
The proposal should be completed prior to the start of EPID 560: Protocol Development (early January)

Spring Term (first year):

- Prepare for and present the protocol in EPID 560: Protocol Development
- Refine the full proposal into its final form based on feedback from discussion in EPID 560 and input from the primary mentor, biostatistics advisor, and third committee member, if appropriate
- Complete design of the appropriate database for the project
- Present at MSCE Protocol Session in late spring

Summer Term (second year):

- Obtain final approval for the full protocol from the primary mentor and thesis committee; Submit the “Full Proposal Form” to the Office of Graduate Training in *July*
- Prepare the IRB submission and submit by *July*
- Once IRB approval/exemption has been obtained, initiate the study
- Forward IRB documentation to the Office of Graduate Training

Fall Term (second year):

- Complete primary, secondary, or database data collection with ongoing data cleaning if possible

Spring Term (second year):

- Complete 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, perhaps even including outlines of results tables to be filled in once the data analysis is complete
- Complete writing of the paper by filling in appropriate tables and results, and writing the discussion section
- If time allows, conduct secondary analyses for additional papers (resist the temptation to do this until after the initial paper is submitted for the degree)

Mini-Proposal

The student is required to draft a single-spaced 2-4 page maximum mini-protocol **by mid-November** of the first fall term. This protocol serves as the basis for the initial approval of the thesis committee to ensure that there are no unexpected surprises in the full proposal. The mini-proposal should serve as the backbone of the full proposal to follow. The mini-proposal should be built around the section of the PHS-424 form known as the Specific Aims (<http://grants.nih.gov/grants/funding/424/index.htm>), which includes a brief justification (to be filled out later in the Background and Rationale section), and an outline of the methods, including sources of data, initial variables to be collected, approximate sample size estimate or power calculations, and an initial analysis plan for the primary outcome. We recommend (but do not require if the work is still ongoing) that the references obtained from the systematic review be included. Verification of approval is provided by submitting the signed “Mini-Proposal Form.”

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 proposal to be completed before the start of the spring semester. The NIH-424 grant application format should be used, including the following sections: Specific Aims; and Research Strategy consisting of Significance, Innovation, and Approach. The Significance and Innovation section replaces the older Background and Significance, and Approach replaces Research Design and Methods. An important part of the Approach is the feasibility exemplified by 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 his/her choice of methods to be used. The Approach section should describe 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, method of data collection, and rationale for each particular outcome in the analysis; 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. Other sections specifically pertinent to the study should be included in a brief section on potential future studies that will result from the study both if the findings are positive or if they are negative. The specific PH-424 guidelines for length (namely 1 page – Specific Aims – plus 12 pages – Research Strategy) are not a formal requirement but we recommend trying to keep the thesis proposal to less than 20 pages, references not included.

During the spring term of the first year, in conjunction with the Protocol Development Course (EPID 560), students are expected to finalize their full thesis research project, with the final product *due in July*. If this is not feasible for whatever reason, students must inform the educational office and let them know when they expect to have this completed. Students should develop this protocol with their advisory team, including multiple reviews and iterations for refinement with his/her primary mentor. The biostatistics advisor should also be involved in the process. The third committee member should be given enough time to review and comment on the proposal as well. Once revisions are complete and the full proposal is approved, students should have their thesis committee sign the "[Full-Proposal Approval Form](#)" for submission to the Office of Graduate Training, indicating that all members of the committee agree on the acceptance of the proposal.

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 proposal 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 Office of Graduate Training in January.

In order to teach students how to better present their protocols, students are expected to work with their mentors in preparing the presentation and practice the full presentation with at least one of their advisors. While we realize that 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 proposal. 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 his or her mentors.

The Final Product

Writing up of the thesis is, again, the primary responsibility of the student, with input from his/her mentor/advisors 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 close to acceptable for submission to a journal once approved by the thesis committee. The primary mentor should be integrally involved in writing a major review of the thesis. Once the mentor's suggestions are incorporated, the thesis must be submitted to the other members of the committee for formal approval. 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 Office of Graduate Training from the primary mentor along with an electronic copy of the 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 Office of Graduate Training 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 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. **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, we expect 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 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: <http://www.nihms.nih.gov/web-help/>

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@penmedicine.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 fellow 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 Office of Graduate Training 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 to his/her mentor and thesis committee. 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 in mid-November to the Office of Graduate Training.
- Thesis Forms—Students are required to submit a signed Mini-Proposal Form, Full-Proposal Form, and Final Thesis Form.
- IRB Certification—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 OASIS 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.
- Graduation Application—The MSCE degree is conferred by the University of Pennsylvania Perelman School of Medicine and is granted in May, August, or December. In order to be considered for conferral of the degree, a student must complete a "graduation application" approximately three months prior to the expected conferral date. Prior to each graduation period, the Office of Graduate Training 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. We strongly advise 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 his/her 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 his/her MSCE thesis (if needed), and substantially improve his/her 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 Services (ORS) can provide information on all such grants (<https://research.upenn.edu/>). We encourage students to work closely 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:

Placing Out of Courses

Students may place out of EPID 510: Introductory Epidemiology and/or EPID 526 & EPID 527: Biostatistics for Epidemiologic Methods I and II with the permission of the faculty instructor and upon passing the final examination for the course(s) in question. The Office of Graduate Training should be contacted to arrange the exemption examination logistics. A score of 80% or better will result in exemption from the course.

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 Office of Graduate Training, 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.

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 Office of Graduate Training to discuss his/her concern. Alternatively, the student may wish to speak directly with his/her MSCE mentor and/or one of the Program Directors.

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 he/she understands 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 Director for the MSCE Degree Program with input from the MSCE Curriculum Committee as needed. Options include studying on his/her own and arranging with the instructor to retake or resubmit the work that led to the unacceptable grade, and 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 Director 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 Director for the MSCE Degree Program, 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.

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.

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 Office of Graduate Training for initial approval and then it will be forwarded to the Associate Dean in the Office of Master's Program for final approval.

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 time line for completion. Both the student's primary mentor and the Executive Education Programs Committee will need to formally review and approve the plan.

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/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

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

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.

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/student-disciplinary-procedures-sexual-assault-violence-relationship-stalking/>

MISCELLANEOUS DETAILS

Penn Card

The Penn Card is the official identification card of the University of Pennsylvania and is required for all students. The PennCard 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.

Canvas

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

Health Care Coverage

Students may receive a letter from Student Health Services (SHS) regarding the Penn Student Insurance Plan (PSIP). Students do not need to act on/respond to this letter if:

He/she is registered for a maximum of 2 credits in a term* **AND** has health insurance through his/her primary employer

**Students are considered full-time in the MSCE program if taking 2.0 credits per term*

PLEASE NOTE: If a student registers for 3 or more credits in a term, he/she will be considered "full-time" by the University and will be subject to the University's health insurance requirement. In this event, the student will be required to submit an online waiver or will be automatically enrolled and billed for PSIP.

Please refer to the SHS website for more details: <http://www.vpul.upenn.edu/shs/>

APPENDIX I: Graduation Requirements (14 total credit units)

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.

Core Courses: 7 credit units

EPID 510	Introduction to Epidemiology	1
EPID 526	Biostatistics for Epidemiologic Methods I	1
EPID 527	Biostatistics for Epidemiologic Methods II	1
EPID 532	Data Management for Clinical Epidemiology	0.5
EPID 542	Measurement of Health in Epidemiology	0.5
EPID 546	Clinical Database Research Methodology	0.5
EPID 560	Issues in Research Protocol Development	0.25
EPID 570	Critical Appraisal of Epidemiologic Methods	0.25
EPID 640	Advanced Topics in Epidemiology	1
EPID 610	Tutorial in Epidemiologic Research	1

Electives: 2-4 credit units

Elective 1		
Elective 2		
*Elective		
*Elective		

Students may choose to focus their elective training in a specific area of interest. The MSCE Program offers additional courses in areas such as *Bioethics*, *Clinical Trials*, *Human Genetics*, *Patient Centered Outcomes Research (PCOR)* and *Pharmacoepidemiology*. Please refer to pages 5-6 in the handbook for course options.

Thesis Credits*: 3-5 credit units

EPID 900	Master's Thesis	3-5*
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*Additional electives may be taken in place of up to two thesis credits provided the student's thesis is progressing on schedule and his/her mentor has approved of the plan. All students are required to complete a minimum of three credits of EPID 900: Master's Thesis registration.

Non-Credit Requirements Checklist

- HIPAA, submit completion certificate to Office of Graduate Training
- CITI, submit completion certificate(s) to Office of Graduate Training
- Individual Development Plans (IDP)—submitted annually in the fall term
- Attendance at CCEB Epidemiology Seminars, 25 sessions—sign-in tracked by Office of Graduate Training
- MSCE Bioethics Training (4 sessions/8 total hours), sign-in tracked by Office of Graduate Training
- MSCE Professional Development Series, sign-in tracked by Office of Graduate Training
- Mini-Proposal, submit to Office of Graduate Training (expected November)
- IRB approval and/or exemption, submit to Office of Graduate Training
- Full-Proposal, submit to Office of Graduate Training (expected July)
- Final Thesis, submit to Office of Graduate Training

APPENDIX II: First Year Schedule

Please refer to the CCEB website and syllabi for official course start/end dates:

<http://www.cceb.med.upenn.edu/course-schedule>

Summer II 2019

- Wednesday, July 10th – *MSCE Orientation/first day of class for incoming students*
- Wednesday, August 21st – *Summer II classes end*

Fall 2019

- Monday, September 2nd – *Labor Day (no classes)*
- Tuesday, September 3rd – *First day of Fall classes*
- Thursday, November 28th & Friday, November 29th – *Thanksgiving break (no classes)*
- Thursday, December 12th – *Fall classes end*

Please note: The MSCE does not observe the Penn fall break in October

**** There are NO Epidemiology classes between the end of fall term and start of spring term ****

Spring 2020

- Wednesday, January 15th – *First day of Spring classes*
- Monday, January 20th – *Martin Luther King Day Observed (no classes)*
- Monday, March 9th through Friday, March 13th – *Spring break (no classes)*
- Wednesday, April 29th – *Spring classes end*

Annual Student Protocol Presentations: April 30th & May 1st; May 7th & 8th

Comprehensive Examination: May 11th & 12th

Summer I 2020

- Tuesday, May 26th – *First day of Summer I session*
- Wednesday, July 1st – *Summer I classes end*

A complete listing of MSCE course descriptions are in Appendix III and available on the CCEB website: <http://www.cceb.med.upenn.edu/course-descriptions>

APPENDIX III: Course Descriptions

For course timing and instructors, please visit the CCEB website:

<http://www.cceb.med.upenn.edu/course-descriptions>

EPID 510 – Introductory Epidemiology (1 course unit)

This course is a series of lectures and workshops, designed to teach basic principles of epidemiologic research design. The course provides an overview of the types of research questions that can be addressed by epidemiologic methods. Topics covered include: definitions of epidemiology; measures of disease frequency; measures of effect and association; epidemiologic study designs, both experimental and non-experimental; and an overview of analysis of epidemiologic studies.

EPID 516 – 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 518 (PUBH 517) – 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 526 – Biostatistics for Epidemiologic Methods I (1 course unit)

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 527 – Biostatistics for Epidemiologic Methods II (1 course unit)

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 532 – Data Management for Clinical Epidemiology (0.5 course unit)

This course provides students with an introduction to the techniques of database management as they apply to clinical research. Students will learn how to design and implement databases to support primary data collection for a variety of study designs, as well as how to use selected secondary data resources for epidemiologic research. This is a laboratory-oriented course in which students will gain first-hand experience through in-class and weekly assignments in performing basic query and reporting operations, migrating data between various file formats, preparing databases for statistical analysis, performing quality

assurance procedures, and creating data management plans for project protocols and grant applications. This course focuses on the practical issues of database management and is intended to support each student's planned research enterprise for the MSCE thesis.

EPID 534 – 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 540 – Injury and the Public's Health (1 course unit)

This course offers students an introduction to the field of injury and violence prevention. As a major cause of death and disability throughout the world, injury is a leading public health problem. Prominent types of injuries to be discussed include those relating to motor vehicles, falls, and firearms. Behavioral, biological, economic, and social issues concerning the implementation of injury reduction policies are emphasized through case studies. The effects of injuries in the workplace, in the home, and those incurred during recreation also are covered.

EPID 542 – 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 546 – Clinical Database Research Methodology (0.5 course unit)

This course will discuss appropriate selection of automated 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 protocol development for database studies and discuss research grant applications related to these studies.

EPID 550 – Clinical Economics and Clinical Decision Making (1 course unit)

This course focuses on the application of decision analysis and economic analysis to clinical and policy research. The course begins with material about the selection, use, and analysis of diagnostic tests using two-by-two tables, likelihood ratios, and ROC curves. The course continues with the introduction of more general tools for decision analysis, including decision trees and other mathematical models. Special emphasis is placed on the assessment and use of utilities in these models. A major focus of the course is the application of economic principles to the evaluation of health outcomes. During seminars, students will carry out practical exercises that include problem solving, critically analyzing published articles, and learning to use computer software that facilitates decision and economic analyses.

EPID 560 – Issues in Research Protocol Development (0.25 course unit)

This is a seminar that 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 proposal for open discussion during one of the seminar sessions.

EPID 570 – 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). For his/her session, each student will critically appraise a journal article and lead the discussion concerning that article.

EPID 575 – 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 580 – 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 584 – 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 610 – 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 proposal, 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 proposal.

EPID 621 – Longitudinal and Clustered Data (1 course unit)

This course serves as an introduction to the principles of and methods for longitudinal and clustered data analysis, with special emphasis on clinical, epidemiologic, and public health applications. Marginal and conditional methods for continuous and binary outcomes are covered as well as mixed effects and hierarchical models, and simulations for power calculations. Each student will be required to participate in 6 labs and complete associated problem sets. They may also use their own data to fulfill these requirements in part. Software will include Stata and R.

EPID 622 – 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 623 – 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.

EPID 624 – Methods in Patient Center 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 625 – Advanced Biostatistical Methods for Multivariable Prediction Models

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 630 – 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 critical 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 634 – 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 636 – Epidemiology Methods of Acute Care (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 638 – Topics in Clinical Trial Design & Analysis (1 course unit)

This course is intended to follow, and be complementary to EPID 630: 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 640 – 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 644 – 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 645 – Cancer Epidemiology, Biomarkers and Prevention (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 646 – 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 652 – 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 656 – 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 658 – 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 664 – 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 666 – Pharmacoepidemiology Research Methods (1 course unit)

The purpose of this course is to explore and integrate concepts and considerations that are key to the conduct of pharmacoepidemiologic research. The format will be a mixture of seminar, instructor-led discussion, student-led discussion, and student presentations. Papers from the applied and methods literature will be used to illustrate concepts and as springboards for discussion. Topics covered include use of automated databases/pharmacogenomics, and approaches to addressing confounding.

EPID 672 – 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 526 and 527). Laboratory sessions will be conducted on students' laptops using STATA software.

EPID 674 – 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 675 – 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 690 – Empirical Bioethics (1 course unit)

Solutions to many of the most pressing problems in modern bioethics require empirically testing assumptions and theories about human behaviors and attitudes. This course will use papers from the primary literature to teach students to understand and use the many methods that have been or could be employed to address questions lying at the intersection of ethics and clinical research. In addition to participating in weekly discussions of these topical and methodologic papers, students will be expected to develop and present a protocol for research designed to explore ethical dilemmas within their own disciplines.

EPID 714 – 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-proposal at the beginning of the term. Each proposal 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 proposal ready for submission.

EPID 775 – 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 900 – 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 999 – Independent Study (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.