EPIDEMIOLOGY 725 - EPIDEMIOLOGIC RESEARCH METHODS - Fall 2016

TIME: Wednesdays 12:20-1:50 pm. Note: class meets only on alternate Wednesdays, as noted below

INSTRUCTORS:

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Lecture Location: MC2306
Small Group Locations: Daniels [MC2306]; **Gammon** [Epi Conference Room]; **Meshnick** [MC2303]

Pre-requisites: This two semester course series (EPID 725/726) is designed to integrate and apply the principles and methods learned in epidemiology and biostatistics courses to the design of epidemiologic studies. The series is required for epidemiology *doctoral* students and offered only to epidemiology majors. Prior to taking this course, students must have completed EPID715 & EPID716. Students must be enrolled in or have completed EPID718. MSPH students must additionally be in their *third or later year* of the program. There is variability around when students take this course. In addition to the course pre-requisites, ***student readiness for this course depends on having a well-developed research topic before the course starts.***

EPID725/726 Course Objectives: In this two course series, students develop a research proposal that reflects their understanding of how the proposed study fits into the field more broadly, is methodologically sound, and conducted in an ethical manner. Successful completion of this course series requires students to demonstrate competency in critical thinking, critical literature review, oral and written communication, ethical research conduct, and all aspects of epidemiologic study design, data collection, and analytic methods.

Students will develop and hone skills required to write and orally present grant proposals and to constructively peer review proposals orally and in writing. Proposal development requires students to synthesize an array of substantive and methodological concerns in order to propose an informative, realistic, and scientifically sound study. For this course series, the student must develop a grant application proposing specific aims that are substantial in scope and contribution. Such proposals usually require substantial investigator time, operational costs (for recruitment, data collection, data access/processing fees, laboratory assays, etc), or sophisticated statistical computing. All proposals, even those that propose hypothetical studies, must appear realistic.

Specific objectives of EPID 725: In EPID725, students learn the structure of a National Institute of Health (NIH) grant proposal and the grant review process. Each student develops a research topic, outlines a study proposal, and develops *Specific Research Aims* modeled after the NIH grant proposal.

Success in EPID725 is facilitated by arriving the first day of class with at least one, preferably two distinct research topics (each with 2-3 specific research questions). To achieve this, students should critically review the literature on the potential topics to identify gaps, challenges, and the important next steps to further the field *before the semester begins*. Early in the semester, one topic will be chosen to further develop into a research proposal. Note: Before the semester begins, *topics should be discussed with an advisor to ensure they are important and feasible*. The final product for EPID725 is a complete Specific Aims document.

****** Small group instructors must judge a student's final Specific Aims as sufficient for development into a full proposal during the spring semester in order for students to progress to EPID726. ******

Specific objectives of EPID 726: In EPID726, students develop a NIH style proposal describing the significance, innovation, approach (study design and implementation strategies), ethical treatment of human subjects, and budget sections of the proposed research. Students provide constructive feedback to peers using a peer review process modeled after the NIH peer review process.

COURSE STRUCTURE: Both EPID 725 and EPID 726 combine lectures and small group sessions.

Lectures: Lectures provide students with tools and resources needed to address critical issues that commonly arise in developing the proposal. Lectures describe specific components required in the proposal and strategies to successfully development of those sections.

Small Groups: Small group sessions provide an interactive opportunity for students to discuss the components of grant proposals, obtain feedback on their proposal at various stages of development, and to provide feedback to peers. Students are assigned to a small group based on their research interests. Attendance and active participation in small group sessions is essential to the success of the course. This includes sharing assignments with the group in a timely manner, reading materials submitted by other students, and preparing written critiques and oral presentations prior to group meetings.

Peer-review: The small group peer review process is set up to mimic a NIH study section (a committee of scientific reviewers). Within the small group, each student's work will be reviewed by two student peer reviewers; and each student will serve as a peer reviewer for two other student applicants. *Prior to* the small group session, peer reviewers must critically read the assignments (from the two peer applicants) and prepare a brief critique. *During* the small group session, peer reviewers orally critique the application (and share written strengths and limitations). Peer reviews should be well prepared and brief (i.e. bulleted format). The review should identify three main strengths and three important weaknesses in a given assignment. Critiques should be fair, to the point, and constructive. Critiques can identify substantive issues, methodological concerns, areas needing clarification, and/or stylistic points. Peer reviewers should *not* suggest solutions.

COURSE MATERIALS: Course materials are available under the following headings on Sakai: *Syllabus* (syllabus, schedule, and assignments)*, Resources* (readings, lecture notes, NIH forms, sample grants). Posted materials (especially grant examples) are for student use only and **not** to be shared broadly.

ASSIGNMENTS:
Formatting Assignments: For all written assignments, use black Arial 11 font, margins of 0.5 all-around, and include references where appropriate. Shared documents should be distributed as a *Word* file, not as a .pdf. Include the name of the PI (i.e. student) in the header of the document and in the document name (e.g. EPID725_Assn1_*student's last name*.docx).

Submitting Assignments: All assignments must be submitted through *Sakai.* Most assignments will be submitted to the whole small group, through *Sakai – Forum.* The final assignment will be submitted only to your small group instructor, through *Sakai - Messages.*

Late assignments: Assignment are due by noon on the date indicated on the schedule. Due dates must be strictly observed as they impact the peer review timeline. Peer reviewers are not required to review late assignments. Graded assignments will be penalized 5% per late day. *Unless student is sick or has unexpected emergency*, absent students should submit assignments on time and submit written peer reviews.

ATTENDANCE is required, unless excused by the small group instructor. During class sessions, students should refrain from using electronic media for purposes not directly related to class *(i.e. avoid personal use of computers/phones during class, especially during small group sessions).*

GRADING: Determined by small group instructors

- 70% Quality of final EPID 725 version of specific aims page (assignment 7)
- 15% Quality, feasibility, and significance of Specific Aims 2nd Draft (Assignment 5)
- 15% Quality of oral peer review of Assignments 4-6

Final grade heavily reflects the quality of the final Specific Aims. Only students earning (P) or (H) will progress to EPID 726. Honors (H) are rare and awarded only for Specific Aims that appear ready to submit to NIH. By

the end of EPID725, students who have not developed the Specific Aims sufficiently to support proposal development activities in EPID726 will not be allowed to take EPID726.

EPID 725 COURSE SCHEDULE:

*** note this class meets on only selected Wednesdays –**

*****written assignments should be submitted through Sakai by noon on the due date -***

Day/Date	Activity	Assignment
W 8/15	Assn1 due	**Submit Assignment 1 by email: Overview of Research Interests
W 8/24	No Class	Critically review literature, develop research topic, discuss ideas with advisor
W 8/31	No Class	**Resubmit Assignment 1 via Sakai.Forum to small group - reflect recent changes
W 9/7 *	**Lecture** **Small Group**	1. Introduction, primary studies, ancillary studies 2. Small group introductions and share Assn 1 - Research Topic Ideas
W 9/14	No Class	Continue to critically review literature and develop research ideas
M 9/19	Assn 2 due	**Submit Assignment 2 to small group to facilitate discussion.
W 9/21*	**Small Group**	Discuss Assignment 2: Students describe their Research Topic (10 minutes each).
M 9/28	No Class	
W 10/5 *	**Small Group**	Assignment 3: Review Specific Aims of Funded Proposals
W 10/12	No Class	
M 10/17	Assn 4 due	**Submit Assignment 4 to small group
W 10/19 *	**Small Group**	Peer Review of Assignment 4 during Small Group
W 10/26	No Class	
M 10/31	Assn 5 due	**Submit Assignment 5 to small group
W 11/2 *	**Small Group**	Peer Review of Assignment 5 during Small Group
M 11/7	Assn 6 due	**Submit Assignment 6 to small group
W 11/9 *	**Small Group**	Peer Review of Assignment 6 during Small Group
W 11/16	No Class	
W 11/23	Assn 7 due	** Final version of Specific Aims ***submitted to instructor only***.
W 11/30	No Class	

ASSIGNMENT 1: Research Proposal Topic

Due 8/15/2015, submit the same or a revised version to your small group through Sakai - Forum **8/31/2016**

Purpose: To ensure student has made sufficient progress in coursework and development of an appropriate research question to facilitate success in this fast-paced, two semester course sequence. While the proposal topic will be refined and further developed throughout the course, it is critical to begin the course with viable research ideas that have been vetted by a research advisor. The topic will also inform small group assignment.

Learning objectives: Students will present brief, basic information about their proposal topic in a manner that reflects familiarity with the literature surrounding the topic and an understanding of the next logical steps for moving the field forward. The proposal topic should be important and impactful. Early engagement of the advisor should help ensure feasibility and result in a better final proposal.

Name:
Email Address:
Program and year in program:_____

Epidemiology Research Area (s) – check all that apply:

Cardiovascular:___	Cancer:___	Genetic:___	Infectious Disease:___
Environmental/Occupational:___	Nutrition:___	Pharmacy:___	Injury:___
Reproductive/Pediatric: ___	Social:___	Psychiatric:___	Other-specify:_____

Academic Advisor:_____

Research/Dissertation Advisor(if different):_____

General research interests:

Potential Research Proposal Topic: Students can list one to two topics. Give a tentative title for each and describe the aims and design in 3-5 sentences. Be as specific as possible.

(1)

(2)

Date research topic(s) reviewed with research advisor:

Briefly note any concerns raised by the advisor related to the topic's contribution to the field, feasibility (in reality or in theory), or alternative topics considered.

Plans to use your proposal/conduct this research:
___ Dissertation ___Submit to funding agency ___Class exercise only

ASSIGNMENT 2: Initial description of grant proposal – due 9/19/16, discussed in class 9/21/16

1. Research question. In a sentence or two, state your research question. This should generally identify the independent (exposure) and dependent (outcome) variables. Make the study question as specific as possible. This need not be a formal hypothesis statement; a short narrative statement is sufficient.

2. Innovation. Characterize in general terms the present state of knowledge on this topic – what is and is not known. Identify the logical next step for building our understanding. Identify the gaps in knowledge that your study will address, or describe the new knowledge or the new application an existing method that your study will contribute. If no one has examined this issue before, provide indirect support from other fields that makes this a reasonable question to ask. You must know and critically synthesize the literature to be able to answer these questions.

3. Public health importance. Indicate why filling the targeted gap is of public health importance, based on the scientific literature on this subject.

4. Study design. Describe the optimal study design and study population to address your research question. Discuss your options. Carefully consider the feasibility for answering this question using the proposed study design or available data. Identify and justify the appropriateness of the choice you make for your proposal in addressing these aims.

5. Exposure and outcome assessment. Discuss the optimal methods currently available to assess your main exposure and outcome of interest. Identify and justify the choices you will make in your proposal. Indicate which measures are based on de novo data collection and which will use extant data.

6. Feasibility. Carefully consider whether the study you propose will work in the timeframe of a 4-5 year grant. Identify the concerns you have and what you need to figure out in order to determine whether your study will be feasible.

ASSIGNMENT 3 – Review the Specific Aims of example grants – due in class 10/5/16

While no written assignment is due, students will orally present their opinions about the Specific Aims of the sample grants during class. Your small group instructor will assign the grants for this session. During small group, all students will be expected to contribute to the discussion. Your written notes about the strengths and limitations of the aims, based on criteria below, may help you organize and deliver an effective oral summary.

Learning Objectives: By reviewing the Specific Aims sections of previously funded NIH proposals, students will become familiar with the content and stylistic approaches for presenting Specific Research Aims. Students will be able to identify key components of the Specific Aims document and appreciate various stylistic approaches that make a strong Aims page and can help sell the topic. Students can then apply these concepts in future assignments as they develop their own Specific Aims.

Pre-class review activity:

Review example grant proposals, NIH review template, and NIH scoring guidelines posted in the *Resources* folder on Sakai. The entire grants are provided for your consideration; yet this semester, we focus only on the *Specific Aims* sections. Critically read the *Specific Aims* page of *all* grants posted for your small group. Be prepared to comment on your score and note the strengths and limitations of the assigned grants during the small group discussion, based on the criteria below.

Overall Impact Score*:* Score Specific Aims for overall impact based on significance, innovation, & feasibility.
Criteria Score*:* Score each criterion (listed below) and support your score using specific, succinct statements to note strengths and weaknesses:

1. Overall Impact - Likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria,

2. Significance - Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

4. Innovation - Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Is the novelty specific to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

5. Approach - Are the overall strategy, study design, methodology, and analyses described, well-reasoned and appropriate to accomplish the specific aims of the project?

Consider discussion surrounding the following impressions:

1. Are the specific aims well written? Criteria you can use are:
    a. Clarity & fluency– ideas have sufficient detail and are presented in easy to follow manner
    b. Limited use of jargon and abbreviations
    c. Accessible to scientists not directly involved in research on the topic of interest
2. If the specific aims were to be fully met by the proposed study, what powerful, sustained influence would this work have on this research field?
3. What is the public health significance of the project?
4. What makes this project innovative?
5. What indicates to you that the applicant can complete the proposed specific aims?
6. Is there any information that you wished the Specific Aims contained?

During the Small Group Session:
All students should be prepared to comment on each criteria for the assigned proposal(s). Details about how the study section formally operates are provided under *Resources* on Sakai. Generally, during Study Section, the primary reviewer provides a numeric summary score and a brief narrative summarizing the aims and significance, then states the strengths and weaknesses under each review criteria. The secondary and tertiary reviewer add additional information or point out particular points worthy of additional emphasis. The whole committee then discusses the scientific merit and importance of the project. At the end of the discussion, the assigned reviewers state their final overall scores, using the guidelines below. All other members of the committee are asked to record their scores privately into the online scoring system. Thus, the committee will likely score grant based on:

1. Oral presentation of a summary of the proposal and scores by reviewer 1
2. Critiques and scores presented by other reviewers
3. The discussion following the critiques provided orally by all reviewers.

Overall Impact or Criterion Strength	Score	Score Descriptor
High	1 2 3	Exceptional Outstanding Excellent
Medium	4 5 6	Very Good Good Satisfactory
Low	7 8 9	Fair Marginal Poor

ASSIGNMENTS 4-7: SPECIFIC AIMS of Research Proposal

Learning Objectives: Students will produce a Specific Aims page modeled after an NIH research proposal (examples available under *Resources* in Sakai). The Specific Aims section of the proposal should relay the significance and innovation of the proposed research and convince reviewers that the research is important, feasible, and of high scientific quality. The Specific Aims section requires careful, succinct writing to ensure the necessary information is included. Through the peer review process, students will be exposed to various writing styles and proposal strategies; which should enhance students' appreciation for how writing and presentation can help excite reviewers about the topic and foster enthusiasm for the rest of the proposal.

The Specific Aims should introduce the topic, build the case that the work proposed under the Specific Aims is needed, and convince the reviewer that this work is important and novel. The Specific Aims should very clearly articulate the research questions or research hypotheses. Follow examples provided under Sakai.

Specific Aims must follow NIH formatting: fit on 1 single-spaced page with ≥0.5 inch margins.

ASSIGNMENT 4: Specific Aims – Draft 1 - due to small group **10/17/2015**
Prioritize focus on fine-tuning the clarity and significance of the research question and ensuring that the proposed aims are feasible with the proposed approach.

- Peer Review of this assignment is due at the time of the small group session **10/19/2016.**

ASSIGNMENT 5: Specific Aims – Draft 2 - due to small group **10/24/2016**

- Peer Review of this assignment is due at the time of the small group session **10/26/2016**
- This assignment is graded (15%)

ASSIGNMENT 6: Specific Aims – Draft 3 - due to small group **11/7/2016**

- Peer Review of this assignment is due at the time of small group session **11/9/2016**
- For Assignment 6, a scoring sheet will be provided during the small group session when the Specific Aims are presented. All group members will anonymously provide a score for each proposal. These scoring sheets will be collected by the small group instructor at the end of the session.

ASSIGNMENT 7: Specific Aims – FINAL VERSION - *due only to small group instructor* **11/23/2016**

- The final version of the Specific Aims must present a solid and important research question that can be feasibly addressed in an R01 style grant.
- This assignment is graded (70%). The quality of this final version determines student's eligibility to enroll in EPID726.

PEER REVIEW of SPECIFIC AIMS DRAFTS (Assignments 4-6) DURING SMALL GROUP SESSIONS:
Peer Review of the Specific Aims will be completed using the NIH scoring template provided under *Resources* on Sakai using the review criteria described in Assignment 2. Students submit drafts of their Specific Aims two days prior to the small group session in which they are discussed. The Assigned peer reviewers must constructively review the assignment and complete the scoring template *using short bulleted phrases to identify key three strengths and three potential challenges* (if any exist) that impact their enthusiasm for the research project. Each criteria should be scored using the NIH scale.

- The cumulative quality of the Peer Reviews contributes to a student's grade (15%)