EPID725 – Research Planning Workshop
TIME: Wednesdays 12:20-1:50 pm. Note: class meets on only specified Wednesdays.

INSTRUCTORS: Email and Small Group Meeting Location:
Julie Daniels: Julie_daniels@unc.edu  MC1305     Steve Meshnick: meshnick@email.unc.edu  MC 2301
Marilie Gammon: gammon@unc.edu  MHRC 0015     Audrey Pettifor: apettifor@email.unc.edu  MC2101G

Lecture location: MC1305

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.

In addition to the formal course pre-requisites, student readiness for this course depends on having a well-developed research topic before the course starts. There is variability around when students take this course. Students should discuss readiness for this course with their advisor or a course instructor.

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 issues 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 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 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 investigators. Prior to the small group session, peer reviewers must critically read the assignments and prepare a brief critique for their two assigned peer investigators. During the small group session, peer reviewers orally critique proposals and share written strengths and limitations. Peer reviews should be well prepared and brief (i.e. bulleted format). Each review should identify three main strengths and three important weaknesses. 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:** Assignment are due by noon on the date indicated on the schedule. Submit assignments through Sakai. Most assignments are submitted to the whole small group through Sakai – Forum. The final assignment is submitted only to the small group instructor, through Sakai - Messages.

**Late assignments:** Due dates are strictly observed because they impact the peer review timeline. Peer reviewers are not required to review late assignments. Assignments will be penalized 5% per late day, unless student is excused due to illness or emergency.

**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).

**GRADES:** 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 version 2 (Assignment 6)
- 15%  Quality of peer review of all Assignments 4-7 (with extra emphasis on Assignment 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:

*Class Meeting; **Assignment due (submit written assignments to small group through Sakai.Forum by noon)*

<table>
<thead>
<tr>
<th>2017 Date</th>
<th>Class Meeting</th>
<th>Assignment</th>
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<tr>
<td>W 23-Aug</td>
<td>None</td>
<td>During this week: complete critical review literature to develop research topic and discuss ideas with advisor (if not already complete). <strong>Assignment 1 due to instructor 8/23/17 (submit via Sakai.Forum)</strong></td>
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| *W 30-Aug | 1- Lecture & Small Group | - Introduction, primary studies, ancillary studies  
- Small group introductions and share Assn 1 - Research Topic Ideas |
| *W 6-Sep  | 2 - Small Group | Discuss Assignment 2: Review Specific Aims of Funded Proposal |
| **T 12-Sep|               | ** Assignment 3 due |
| *W 13-Sep | 3 - Small Group | Discuss Assignment 3: Students describe Research Topic |
| **T 19-Sep|               | ** Assignment 4 due |
| *W 20-Sep | 4 - Small Group | Peer Review and Discuss Assignment 4 – focus on research question |
| **T 26-Sep|               | ** Assignment 5 due |
| *W 27-Sep | 5 - Small Group | Peer Review 5 – Specific Aims – Version 1 |
| W 4-Oct   | None          | |
| **T 10-Oct|               | ** Assignment 6 due |
| *W 11-Oct | 6 – Small Group | Peer Review of Assignment 6 – Specific Aims - Version 2 (*graded) |
| W 18-Oct  | None          | |
| W 25-Oct  | None          | |
| **T 31-Oct|               | ** Assignment 7 due |
| W 1-Nov   | None          | |
| W 8-Nov   | None          | |
| W 15-Nov  | TBD           | Small Group or Individual Meeting – per Instructor |
| W 22-Nov  | None          | |
| W 29-Nov  | None          | |
ASSIGNMENT 1: Research Proposal Topic

Purpose: To ensure student has made sufficient progress in the 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 placement.

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:

Program and Year in Program:

Academic Advisor: Research/Dissertation Advisor if different:

Epidemiology Research Area (s) – rank order areas that apply to you:
__Cancer ___Cardiovascular ___Environment/Occupation ___Genetic ___Infection
___Injury ___Mental Health ___Nutrition ___Pharmacy ___Reproduction/Pediatric
___Social ___Other, specify:

List your general research interests:

Potential EPID725-726 Research Proposal Topic: List one to three topics you are considering developing into a research proposal. Be as specific as possible about the research question or hypothesis and the data source/ study design.

(1)

(2)

Note the date research topic(s) reviewed with research advisor and 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 – Review the Specific Aims of example grants

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 Activity: Small group instructor will assign the grants for this session at least one week before the session. 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. While no written assignment is turned in, students should use the NIH review template to guide their review of example grants. Written notes about the strengths and limitations of the aims, based on criteria below, may help students organize and deliver an effective oral summary and critique about the Specific Aims of the sample grants during class.

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, and methodology 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?
In-Class Activity:
All students should be prepared to comment on 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.

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<thead>
<tr>
<th>Overall Impact or Criterion Strength</th>
<th>Score</th>
<th>Score Descriptor</th>
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<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
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<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
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<tr>
<td></td>
<td>5</td>
<td>Good</td>
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<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
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<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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ASSIGNMENT 3: Initial description of grant proposal

Learning Objectives: Careful consideration of the developing research questions should prompt students to assess that their topic and approach are appropriate, impactful, and feasible. This assignment should help students to improve the rigor of their research questions and identify the challenges they may face.

Written Assignment due to Sakai:
1. Research question. In a sentence or two, state your research question(s). Identify the independent (exposure) and dependent (outcome) variables. Make the study question as specific as possible. This should include a formal hypothesis statement. A more detailed research questions will draw out more constructive and useful feedback from the peer group.

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 clinical/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 the feasibility study design options for your planned design. Provide carefully considered rationale for answering this question using the proposed study design or available data.

5. Exposure and outcome assessment. Discuss the optimal methods currently available to assess your main exposure and outcome of interest. Indicate which measures are based on de novo data collection and which will use extant data. Provide rationale for decisions and discuss feasibility.

6. Feasibility. Carefully consider whether the study you propose will work in the timeframe of a 3-5 year grant. Identify the concerns you have and what you need to figure out in order to determine whether your study will be feasible.

In-Class Activity: Students present their topic, initial aims, and approach. Students can raise questions or concerns they have about the impact or feasibility of the topic and obtain suggestions from the peer group to strengthen the clarity or rigor of the proposed research topic and design.

ASSIGNMENT 4: Critical Consideration of the Research question

Learning Objective: This assignment is NOT the full-page version of the Specific Aims, but instead focuses on strengthening the specific research questions and hypothesis statements. The goal is to critically consider multiple options for framing the research questions and identify problems or holes in the research that can be addressed early to tighten the work and improve the impact. Students will constructively critique a working draft of research aims and hypotheses to 1) improve the rigor of the research question, 2) highlight the impact of the proposed research questions 3) ensure the questions are feasible and discuss possible design options.

Pre-Class Activity:
- Reconsider the research questions presented last week and critically review the literature and available research resources to modify the research questions to best fill the gaps in knowledge on this topic and pursue the most important 'next steps' in this line of research.

Written assignment due to Sakai by noon the day before class:
- Present the overall aims and each research question in at least two ways.
- Consider at least one alternative study design and discuss the strengths and limitations of each approach.

In-Class Activity: Peer Review Assignment 4. All students should read all Students Specific Aims prior to class. Peer reviewers will provide constructive feedback regarding on the focus of the research question.
ASSIGNMENTS 5-7: 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.

Written Assignments due to Sakai:
The Specific Aims should introduce the topic, build the case that the work proposed under the Specific Aims is necessary, and convince the reviewer that this work is important and novel. The Specific Aims should very clearly articulate the research questions and what the work will contribute. Follow examples provided in Sakai.

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

ASSIGNMENT 5: Specific Aims – Draft 1
- Prioritize the clarity of the research question. Also note the significance of the problem and novelty of the approach/solution. Ensure that the proposed aims are feasible with the approach planned.
- Peer Review of this assignment is due at the time of the small group session.

ASSIGNMENT 6: Specific Aims – Draft 2
- All aspects of the Specific Aims should be well-developed and promote the importance of the proposed research questions by highlighting key innovative or significant aspects of this work.
- This version of the Specific Aims is graded (15%) and instructor will provide written feedback.
- Peer Review this assignment using the NIH template - due at the time of the small group session.
- During the peer review of Assignment 6, peer reviewers will provide overall score. All group members will anonymously provide a final score for each proposal/Specific Aims using a scoring sheet provided by the instructor. Scoring sheets will be collected by the small group instructor and the mean total score will be provided to the student with the instructor’s written feedback.

ASSIGNMENT 7: Specific Aims – FINAL VERSION - due only to small group instructor.
- This final version of the Specific Aims should incorporate all useful feedback and 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 based on the NIH scoring template provided under Resources on Sakai using the review criteria described in Assignment 2. Students submit assignments one day 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 three key strengths and three potential challenges (if any exist) that impact their enthusiasm for the research project. Score using the NIH scale.
- The cumulative quality of the peer reviews contribute to a student’s grade (15%)