TIME: Tuesdays 3:30-4:45pm.  Note: classes are on selected Tuesdays only, as outlined below.
Lecture Location:  RO 228

INSTRUCTORS:          Small Group
Julie Daniels, PhD, Office: 2102C McGavran-Greenberg; email: Julie_daniels@unc.edu  HO 1001
Marilie Gammon, PhD, Office: 2104E McGavran-Greenberg; email: gammon@unc.edu   HO 0015
Steven Meshnick, PhD, Office: 3301 Hooker Res Ctr; email: meshnick@email.unc.edu     HO 3005
Til Sturmer, MD, PhD, Office: 2105E McGavran-Greenberg; email: sturmer@unc.edu  HO 2005

Course Objectives: This two semester course series (EPID 726/726) 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 this course, students must have completed EPID715 & EPID716.  Students must be enrolled in or have completed EPID718.  MSPH/PhD students must additionally be in their third or later year of the program. Student readiness for this course also depends on having a well-developed research topic before the course begins.

Development of a research proposal employing epidemiologic methods should reflect the student’s ability to critically review scientific literature, understand of how the proposed study fits into the field more broadly, design a methodologically sound study, and conduct research in an ethical manner.

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, the proposed study must involve new recruitment and data collection or be an ancillary study that uses existing study resources, yet requires some new data collection, data validation, or assay of samples. Even proposals of hypothetical studies must be realistic. Students hone skills required to write and orally present grant proposals and to constructively peer review proposals orally and in writing. Successful completion of this course series requires students to demonstrate competency in critical thinking and literature review, oral and written communication, ethical research conduct, and all aspects of epidemiologic study design, data collection, and analytic methods.

Specific objectives of EPID 725 (Fall 2015): 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). One topic is further developed into Specific Aims over the semester. Topics should be informed by a critical literature review and discussed with the advisor to ensure they are important and feasible. Progression into EPID726 requires successful completion of EPID725 (approved research question and specific aims reflecting plans for a feasible epidemiologic study design).

Specific objectives of EPID 726 (Spring 2015): 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. Full participation in group discussions and peer review are critical. Accordingly, 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).
Lectures: Lectures will be few in number, but provide students with tools and resources needed to address critical issues that arise in developing the proposal.

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 prior to group meetings, and preparing written critiques and oral presentations prior to group meetings.

Peer-review: Within each small group, two student peer reviewers are assigned for each student and each student serves as a peer reviewer for two peers. Peer reviewers are expected to critically read submitted assignments and prepare written comments that are emailed to the grant writer before the group meets, then present the key points orally during small group sessions. Oral presentation of peer reviews must be succinct during group sessions; thus, comments should be well prepared, edited, and brief (preferably bulleted format).

The small group peer review process is set up to mimic a NIH study section (a committee of scientific investigators). To be as objective and as realistic as possible, critiques should be worded in the third person and oral presentations of the critique should address the small group (not the grant writer). Peer reviews should identify 3 main strengths and 3 important weaknesses (bulleted format). Critiques should be fair, to the point, and constructive. The critique can address substantive, methodological and/or stylistic issues. Peer reviewers should identify strengths, problems, or areas needing clarification, but not suggest solutions.

COURSE MATERIALS: Course materials are available on Sakai under the following headings: Syllabus (Syllabus & Assignments) and Resources (readings, slides, NIH forms, sample grants). Materials posted on Sakai (especially grant samples) are for student use only and are not to be shared beyond the class.

ASSIGNMENTS: Assignment due dates are indicated on the course schedule and should be strictly observed. All written assignments should be submitted electronically to the designated recipients. For written assignments, use black Arial 11 font, margins of 0.5 all-around, and include references where appropriate. All shared documents should be distributed as a Word file, not as a .pdf. Include the name of the PI in the header of the document and the topic and PI name in the file name (e.g. EPID725_Assn1_student’s last name.docx).

POLICIES - Late assignments and student absence: Students must submit assignments to designated recipient by 10am on the due date. Late assignments adversely impact the timeline for peer review; thus may not receive the benefit of peer review and will be reflected in the student’s grade. Attendance is required, unless excused by instructor. Unless student is sick or has unexpected emergency, absent students should submit assignments on time and submit written peer reviews.

GRADING: Determined by small group instructors.

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
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<tbody>
<tr>
<td>5%</td>
<td>Initial description of grant proposal (Assignment 2)</td>
</tr>
<tr>
<td>5%</td>
<td>Critique of specific aims page of existing grants (Assignment 3)</td>
</tr>
<tr>
<td>80%</td>
<td>Quality of final EPID 725 version of specific aims page (assignment 6)</td>
</tr>
<tr>
<td>10%</td>
<td>Quality of oral peer review (Assignments 4 &amp; 5)</td>
</tr>
</tbody>
</table>

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. Those earning low pass (L) or incomplete (I) may need to repeat the course before progressing to EPID726.
Assignment formatting and submission process: For all assignments, use black Arial 11 font, margins of 0.5 all-around, and include references where appropriate. All 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). Send all assignments to the designated person or group (noted on assignment and schedule).

Late policy: To give the reviewers sufficient time, students must submit assignments/draft proposals to the *entire small group (including the instructor)* by the designated time. The small group discussions rely on peer reviewers receiving documents from the PI (student) in time to provide constructive peer review. Late assignments will not receive the benefit of peer review. While not all assignments are graded by instructors, continual late submissions to the group will be noted and your overall grade will be adjusted accordingly. Graded assignments that are late will be penalized 5% per day. Most funding agencies do not accept late proposals. Consequently, students are expected to comply with the due dates for this course.

ASSIGNMENT 1: Research Proposal Topic
Submit to juliedaniels@unc.edu by 10am 8/27.

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:

Epidemiology Research Area (s) – check all that apply:
___Cancer  ___Cardiovascular Disease ___Environment/Occupation ___Genetic
___Infection  ___Injury ___Nutrition ___Pediatric
___Pharmacy  ___Psychiatry ___Reproduction ___Social
___Other, specify:

Academic Advisor:

Research/Dissertation Advisor:

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
Submit to Small Group via Sakai by 10am 9/14

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 gaps in knowledge that your study will address. You must dig into the literature and critically synthesize it to be able to answer these questions. Indicate what new knowledge or application the proposed 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. If related studies have been done, indicate how the proposed study will improve upon them or resolve specific gaps that left in our understanding.

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. Identify and justify the choice you make for your proposal.

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. Directed acyclic graph. Draw the DAG of potentially influential variables in the exposure-outcome relationship of interest. This should include a main exposure, a main outcome, and a number of covariates (potential confounders or effect measure modifiers).

7. Statistical analysis. In general terms, describe the statistical approach(es) required to evaluate the main research question.

8. Preliminary data. Briefly describe the preliminary data you may need for your grant proposal.

9. Investigators and environment. Describe the fields of expertise needed for successful completion of the study. Describe your expertise related to the proposed topic. Describe the strengths of the team you will propose.

*Note: Careful development of each of these sections will facilitate future assignments, where students draft compelling specific aims. Students are encouraged to continue to develop these sections throughout the semester, using the literature and comments of peer reviewers, to set the stage for EPID726
ASSIGNMENT 3a and 3b – Peer review of example grant Specific Aims

a) Submit the assigned written review to small group leader via Sakai by 3:00pm 9/22

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 and writing activity:
Review example grant proposals, NIH review template, and NIH scoring guidelines posted in the Resources folder on Sakai. Although the entire grants are provided for your consideration, this semester we focus only on the Specific Aims section. Critically read the Specific Aims of all grants posted for your small group. You are assigned as a primary reviewer for only one proposal. For the assigned proposal, critique the Specific Aims page using the criteria below. As the primary reviewer, prepare a written summary of Specific Aims providing your overall impression and reflecting specific review criteria (Specific Aims may not contain all information in review categories). Provide rationale for your score by stating the main strengths and weaknesses for each criterion using the NIH review template-bulleted format. As you consider the review criteria below, you may find that the single-page Specific Aims section is too brief to allow complete judgement regarding the project’s approach – but think through this critique as you review the Specific Aims and consider how well the research idea was presented, whether it comes across as important, and whether the overview of the approach seems appropriate. The review criteria presented here are described so that you will understand what should inform the specific aims and research approach you will develop.

Overall Impact: Summary of the Specific Aims, highlighting significance, innovation, and feasibility.
Specific Review Criteria (score each criterion and support your score using specific, succinct bulleted statements to note strengths and weaknesses for each criterion described below):

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?

3. **Investigators** - Are the investigators (PIs, collaborators, and other researchers) well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Does the investigator team have experience and complementary/integrated expertise?

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, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

6. **Environment** - Will the scientific environment contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
Assignment 3b: For Small Group session 9/22, prepare to discuss your critique of Specific Aims:
We will follow NIH Study Section procedures during small group. All students should be prepared to serve as
the primary reviewer for the proposal they are reviewing. The general process is described below; additional
details about how the study section operates are provided under Resources on Sakai.

In a typical NIH review, two or three reviewers are assigned to read the entire grant proposal. Their initial
impressions are often shaped by the title, abstract, and specific aims page, then reinforced by the approach. Other study section members may read sections of proposals that were not assigned to them, but most unassigned reviewers will focus only on the Specific Aims.

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 by reviewer 1
2. Critiques presented by reviewers 1, 2 and 3
3. The discussion following the critiques provided orally by the 3 reviewers.

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

Consider discussion surrounding the following questions:
1. Is the specific aims page well written? Criteria you can use are:
   - Clarity and fluency
   - Limited use of jargon and abbreviations
   - Accessible to scientists not directly involved in research on the topic of interest
   - Balanced amount of detail

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 aspects of the approach are presented to indicate they can answer the proposed specific aims?

6. Is there any information that you wished the Specific Aims contained?
ASSIGNMENTS 4, 5, 6: 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.

ASSIGNMENT 4: Specific Aims – Version 1
10/13 PI submits Specific Aims to small group (post to Sakai)
10/19 Peer Reviewers submit written Peer Review to small group (post to Sakai)
10/20 Small Group meeting to discuss highlights of Assignment 4 and peer review.

ASSIGNMENT 5: Specific Aims – Version 2
11/3 PI submits Specific Aims to small group (post to Sakai)
11/9 Peer Reviewers submit written Peer Review to small group (post to Sakai)
11/10 Small Group meeting to discuss highlights of Assignment 4 and peer review.

ASSIGNMENT 6: Specific Aims – Final Version
11/17 PI submits Specific Aims to ONLY small group instructor
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. Grade on the final version determines eligibility to enroll in EPID726.

PEER REVIEW of SPECIFIC AIMS DRAFTS (Assignments 4 and 5): 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 one week prior to the small group session in which they are presented. The Assigned peer reviewers must then constructively review the submitted document and complete the NIH scoring template – using short bulleted phrases to identify key three strengths and three potential challenges that impact their enthusiasm for the research project. Each criteria should be scored using the NIH scale (see assignment 3).

***Peer Reviews must be posted to Sakai by 10am the day before the small group meeting.

***Prior to small group meeting, students should review the second critique for the proposal they are reviewing as well as the critiques of their own proposal by the two peer reviewer

For Assignment 5, 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.
# EPID 725 COURSE SCHEDULE:

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
<th>Assignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tu 8/18</td>
<td>-</td>
<td>No class</td>
</tr>
<tr>
<td>Tu 8/25</td>
<td>Lecture</td>
<td>Introduction, primary studies, ancillary studies</td>
</tr>
<tr>
<td>Th 8/27</td>
<td>Due 10am</td>
<td>Assignment 1: Research Topic – Submit to <a href="mailto:Juliedaniels@unc.edu">Juliedaniels@unc.edu</a></td>
</tr>
<tr>
<td>Tu 9/1</td>
<td>Small group</td>
<td>Each student orally presents topic (3 minutes), group provides feedback</td>
</tr>
<tr>
<td>Tu 9/8</td>
<td>-</td>
<td>No Class</td>
</tr>
<tr>
<td>Mo 9/14</td>
<td>Due 10am</td>
<td>Assignment 2: Initial description of grant proposal - Submit to Small Group, No Class</td>
</tr>
<tr>
<td>Tu 9/15</td>
<td>Small group</td>
<td>Each student orally presents Assignment 2 (3 min); then two peer reviewers (and other small group members) pose questions for student to consider (5 min)</td>
</tr>
<tr>
<td>Tu 9/22</td>
<td>Small group</td>
<td>Assignment 3: Review Specific Aims of funded proposals. –Submit the one assigned written review to Small Group Instructor only. Prepare for oral discussion with whole group.</td>
</tr>
<tr>
<td>Tu 9/29</td>
<td>-</td>
<td>No Class</td>
</tr>
<tr>
<td>Tu 10/6</td>
<td>-</td>
<td>No Class</td>
</tr>
<tr>
<td>Tu 10/13</td>
<td>Due 10am</td>
<td>Assignment 4: Specific Aims – Version 1; Submit to Small Group; No Class</td>
</tr>
<tr>
<td>Mo 10/19</td>
<td>Due 10am</td>
<td>Post peer review of Assignment 4 on Sakai for other reviewer and PI to read before class</td>
</tr>
<tr>
<td>Tu 10/20</td>
<td>Small group</td>
<td>Peer review of Assignment 4: Oral summary of proposal and constructive critique by reviewer 1 (5 min); constructive critique by reviewer 2 (3 min)</td>
</tr>
<tr>
<td>Tu 10/27</td>
<td>-</td>
<td>No Class</td>
</tr>
<tr>
<td>Tu 1/13</td>
<td>Due 10am</td>
<td>Assignment 5: Specific Aims –Version 2; Submit to Small Group; No Class</td>
</tr>
<tr>
<td>Mo 11/9</td>
<td>Due 10am</td>
<td>Post peer review of Assignment 5 on Sakai for other reviewer and PI to read before class</td>
</tr>
<tr>
<td>Tu 11/10</td>
<td>Small group</td>
<td>Final Meeting - Peer review of Assignment 5: Oral summary of proposal and constructive critique by reviewer 2 (5 min); constructive critique by reviewer 1 (3 min)</td>
</tr>
<tr>
<td>Tu 11/17</td>
<td>Due 10am</td>
<td>Assignment 6: Specific Aims – Final; Submit to Group Instructor only; No Class</td>
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<tr>
<td>Tu 11/24</td>
<td>-</td>
<td>No Class</td>
</tr>
<tr>
<td>Tu 12/1</td>
<td>-</td>
<td>No Class - Instructor meeting to discuss grades and progress to EPID 726</td>
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