

EPIDEMIOLOGY 726 - EPIDEMIOLOGIC RESEARCH METHODS

Spring 2014 Syllabus

TIME: Tuesdays and Thursdays, 11:00am – 12:15pm

LECTURE LOCATION: 228 Rosenau

SMALL GROUP LOCATION: TBA

INSTRUCTORS:

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OBJECTIVES: The course is designed to apply the principles and methods learned in introductory epidemiology, epidemiologic methods, and biostatistics courses to the design of epidemiologic studies. In EPID 725, you learned the structure of a National Institutes of Health (NIH) grant, identified a research topic, outlined a proposed study, and developed study aims and grant abstract. In EPID 726 we will emphasize study significance, innovation, design and implementation strategies, rather than methods of statistical analysis that are addressed in other courses.

Proposal development requires attention to an array of substantive and methodological concerns in order to propose an informative, realistic, and scientifically justified study. To maximize the educational experience, it is essential that there be some primary data collection included in the study, e.g., interviews, laboratory assays, or record abstraction. Ancillary studies are acceptable.

COURSE STRUCTURE: The course is organized into complementary "large group" lectures/panel discussions and "small group" sessions. Lectures/panel discussions are presented by faculty instructors and focus on critical issues you will confront during proposal development. They are intended to provide you with tools and resources for addressing these issues. Lectures will last 15-30 minutes with faculty panel discussions lasting the remainder of the class time. Students are expected to read the assignments prior to the lectures, and to participate in the faculty panel discussions. Your small groups again provide an opportunity for you and your fellow students to discuss **your** and their grant application progress with an instructor and other students.

The order of sessions is designed to follow the general sequence of a NIH R01 research grant proposal. Please be aware, however, that you need not wait until a particular component is addressed to begin exploring it. For example, one cannot estimate sample size until deciding on study design, measurements, and analysis methods. Consequently, you will need to work on many sections of the proposal simultaneously, rather than in strict sequence. This is also an iterative process because modifications must be reconciled with other sections. Therefore ample time is required for the finished product.

SMALL GROUPS: Your small group will typically contain the same members as it did for EPID 725, with approximately 10 students per small group matched to the extent possible with the interests of the faculty. It is desirable to maintain consistent groups to maximize group rapport. Group members can

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then become familiar with the other proposals in their group and discuss new issues with minimal review. If you are not pleased with your assignment, it is up to you to identify someone with whom you can potentially trade – and the switch will need to be approved by your respective small group instructors.

It is essential that you be an active participant in the small groups-- by sharing your current assignment/draft proposal in a timely manner and, as discussed in more detail below, in preparing your peer review comments on others' research. Each small group session has an accompanying assignment (which will require you to write a new section of your draft grant application) that must be completed prior to the group meeting and emailed to your small group (both the instructor and fellow students) by 10 am the day prior to meeting. For example if your group meets at 11:00am on January 30th, your revised grant application (that includes the new, highlighted material that has been added to address the issues raised in the course assignment) must be emailed to group members by 10 am on January 29th. Make sure to have the shared version of your revised grant draft (that includes the newly added materials for the assignment) on hand for reference during the group meeting. Assignments will not be graded, but they will be reviewed to verify their completion, stimulate the peer review process, and ensure that you are working towards the timely completion of your proposal. You will be provided brief comments on your assignments from your peer reviewers.

PEER-REVIEW: Two reviewers are assigned per student applicant, with one designated as the primary reviewer and the second as the secondary reviewer. All homework assignments are expected to be read by all students in a small group prior to the small group meeting, while the primary and secondary reviewer are expected to prepare brief written comments to be shared orally in class.

For the small group peer review, for each grant reviewed, the primary reviewer will first provide a very brief (two or three sentence) overview of the student's draft grant application -- specifically that section that pertains to the assigned homework. For the peer critique, both the primary and secondary peer reviewers will identify/list, at most, three positive and three negative issues in the revised grant application, focusing on the newly added section(s) written to address the issues raised in the current assignment. The review comments can include substantive, methodologic and/or stylistic issues. The peer reviewers are responsible for identifying pros and cons about the written assignment/draft grant application – but do not recommend solutions. Small group time is limited, and consequently the review time for each assignment is by necessity short. Thus, peer review comments should be brief, using a bulleted format (e.g., a bullet for each issue identified).

To increase professional development, the small group peer review process is set up to mimic a NIH study section (a committee of scientific investigators who meet to review grant applications at regularly scheduled intervals). Therefore, to be as realistic as possible, we request that you prepare your review in third person, and orally address the group (rather than the grant writer) – because the grant applicant/writer is never present at the time of the review of their application at NIH. For small group, however, the grant writer is permitted to remain in the room as an observer, and is asked to not interrupt the review process – although at the completion of the short review, they can ask the reviewers for clarification.

WRITTEN PEER CRITIQUE: Each student is responsible for providing a written critique of the proposal (second draft) for the two small group members whose progress you review on a regular basis. The written peer reviews of the second grant drafts will be graded, and are due right before spring break (see schedule).

Reviewers should use the NIH grant application “summary critique” template that is posted online (at NIH, and is included in the course materials on Sakai (<http://sakai.unc.edu>)), limiting the critique of each draft grant application **to a maximum of two pages in length**. The NIH review form includes

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room to assign scores and to identify the pros and cons regarding the grant application on five key criteria: significance; innovation; investigators; approach; and environment. Focus on a few positive and negative issues for each of the five key criteria – identifying issues that impact the integrity of the proposed project. USE A BULLETED FORMAT AND KEEP THE CRITIQUES BRIEF. At NIH, the reviewers prepare these written summary critiques to present to study section (and the grant writer is not present), so do not address your written comments directly to the grant writer. For this course, the critiques will be sent to the small group (including the small group instructor). There will then be a small group meeting to discuss feedback, with a maximum of 10 minutes of discussion allotted per proposal.

LATE POLICY: To give the primary and secondary reviewers sufficient time to review the assignments prior to class, students must submit their assignments/draft proposals to the entire small group (including the instructor) by 10 am the day before the small group discussion, as stated above. Other submissions to the small group instructor (First Proposal draft (abstract, specific aims, significance & innovation); Peer Critique; and Third Draft/Final Submission) and peer reviewer (Second Proposal draft for peer review) must be submitted by 5 pm on the due date. Graded submissions that are late will be penalized 5% per day they are late. While individual assignments are not graded by instructors, continual late submissions to the group will be noted and your overall grade will be adjusted accordingly. **NIH, and most other funding agencies, do not accept late proposals. Consequently, students are expected to comply with the due dates and times in this grant writing course.**

COURSE MATERIALS: Readings, assignments, lecture notes, and NIH forms will be accessible online at the course website (<http://sakai.unc.edu>) or distributed during class.

Examples of funded grant proposals written by course instructors, former students enrolled in this course, and other members of the department will be placed in a folder on Sakai. Refer to these frequently; selecting any sections of the proposals that are pertinent to the problems as you confront them. **Please only use these grants for your reference and do not distribute them as they include confidential material and are not provided as public documents.**

GRADING: Grading has five components, each determined by your small group instructor. We will emphasize the quality of the final proposal in evaluations, but some consideration will also be given to the amount of progress made over the course of the semester.

- 10% First draft of the Research Proposal (Abstract, Relevance, Specific Aims, Significance & Innovation, only)
- 10% Written Peer Critiques of the Second draft of the Research Proposal (Abstract, Specific Aims, Significance, Innovation, Approach, only)
- 10% Lectures/Panel Discussions Participation & Small Group Participation
- 10% Oral Presentation
- 60% Third draft/Final Research Proposal (Abstract, Relevance, Specific Aims, Significance, Innovation, Approach, Human Subjects, Budget/Budget Justification)

FINAL GRADES: To earn an H, the final proposal must be of sufficient quality to be submitted to NIH as an R01, R21, or R03 with minimal revisions. Proposals that would require some additional work will earn a P. Those that fall below this standard, or students with repeated poor performance on written assignments and/or chronically late submissions, can expect at best to receive an L. A very weak performance on multiple aspects may require repeating the course sequence.

Date	Class Topic	Instructor*	Student Assignment
January			
Th 9	Lecture + Panel Discussion: Course Structure, and Significance & Innovation	Gammon All	Read: Jensen/Gammon, Buckley/Engel, Gordon-Larsen, North, Van Rie & Wohl applications -- focus on significance & innovation before class. Bring grant copies to discuss in class.
M 13	NO CLASS		Email: Revised Abstract/Specific Aims due to small group by 10 am
Tu 14	Small Groups: PEER-REVIEW of Revised Abstract/Specific Aims	All	Discuss: REVISED ABSTRACT/SPECIFIC AIMS FROM EPID725
Th 16	Lecture + Panel Discussion: Professional Grant Writing -- (1) Scientific Writing & (2) Other Funding Sources	Meshnick All	Read: Jensen/Gammon, Buckley/Engel, Gordon-Larsen/North, Van Rie & Wohl applications -- focus on scientific writing style
Tu 21	Small Groups: Individual meeting with small group instructor to discuss issues relevant to the first draft of proposal	All	NOTE: Small group instructors will NOT read early drafts of your proposal for/at this meeting; instead come prepared to seek advice on unresolved issues encountered while developing this first draft.
Th 23	Lecture + Panel Discussion: Study Population, Participant Recruitment and Retention	Heiss All	Read: Jensen/Gammon, Buckley/Engel, Gordon-Larsen, North, Van Rie & Wohl applications -- focus on study population before class. Bring grant copies to discuss in class.
F 24	NO CLASS		Email: First Proposal Draft (Abstract, specific aims, significance & innovation) to small group by 5 pm
Tu 28	Lecture + Panel Discussion: Exposure/Outcome Assessment, Validation Studies	Gammon All	Read: Jensen/Gammon, Buckley/Engel, Gordon-Larsen, North, Van Rie & Wohl applications --focus on exposure/outcome before class. Bring grant copies to discuss in class.
Th 30	Small Groups: PEER-REVIEW of First draft of proposal	All	Discuss: Peer-review of first proposal draft
February			
M 3	NO CLASS		Email: Assignment 2 to small group by 10 am
Tu 4	Small Groups: PEER-REVIEW of Assignment 2	All	Discuss: Assignment 2 -- Study design
W 5	NO CLASS		Email: Assignment 3 to small group by 10 am
Th 6	Small Groups: PEER-REVIEW of Assignment 3	All	Discuss: Assignment 3 -- Study Population
M 10	NO CLASS		Email: Assignment 4 to small group by 10 am
Tu 11	Small Groups: PEER-REVIEW of Assignment 4	All	Discuss: Assignment 4 -- Exposure/outcome assessment
Th 13	Lecture + Panel Discussion: Data Analysis	Van Rie All	Read: Jensen/Gammon, Buckley/Engel, Gordon-Larsen, North, Van Rie & Wohl applications -- focus on data analysis before class. Bring grant copies to discuss in class.
Tu 18	Lecture + Panel Discussion: Human Subjects/Research Ethics	Meshnick All	Read: Jensen/Gammon, Buckley/Engel, Gordon-Larsen, North, Van Rie & Wohl applications -- focus on human subjects before class. Bring grant copies to class
W 19	NO CLASS		Email: Assignment 5 due to small group by 10 am
Th 20	Small Groups: PEER-REVIEW of Assignment 5	All	Discuss: Assignment 5 -- Statistical analysis
Tu 25	Lecture + Panel Discussion: Resources/Environment, and Budget/Budget Justification	Gammon All	Read: Posted applications -- focus on budget/budget justification before class; bring grant copies to class
Th 27	NO CLASS -- <i>Time to work on second draft of proposal</i>		Finalize: Second draft of proposal
F 28	NO CLASS		Email: Second proposal draft: abstract and research plan (specific aims + research strategy, BUT NO STUDY POWER) to small group by 5 pm
March			
Tu 4	Lecture: Sample Size and Study Power I	Bradshaw All	Read: Buckley/Engel & Wohl applications -- focus on study power before class. Bring grant copies to discuss in class
Th 6	Lecture: Sample Size and Study Power II	Bradshaw All	Read: Jensen/Gammon application -- focus on study power before class. Bring grant copy to discuss in class
F 7	NO CLASS		Email: Peer Critique to small group by 5 pm
Tu 11	<i>Spring Break</i>		

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Th 13	<i>Spring Break</i>		
Tu 18	Small Groups: PEER-REVIEW of second draft of the proposal	All	Discuss: Peer-review of second proposal draft
W 19	NO CLASS		Email: Assignment 6 due to small group by 10 am
Th 20	Small Groups: PEER-REVIEW of Assignment 6	All	Discuss: Assignment 6 -- Sample size/power
Tu 25	Lecture + Panel Discussion: How to give an oral presentation for this class, and sign up for student presentation day & time	Beard All	Bring calendars to class
W 26	NO CLASS		Email: Assignment 7 due to small group by 10 am
Th 27	Small Groups: PEER-REVIEW of Assignment 7	All	Discuss: Assignment 7 -- Human subjects/research ethics
M 31	NO CLASS		Email: Assignment 8 due to small group by 10 am
April			
Tu 1	Small Groups: PEER-REVIEW of Assignment 8	All	Discuss: Assignment 8 -- Study logistics/timeline
W 2	NO CLASS		Email: Assignment 9 due to small group instructor by 10 am
Th 3	Small Groups: Individual Meetings with Small Group Instructor to review Assignment 9	All	Discuss: Assignment 9 -- Budget/budget justification & resources
Tu 8	NO CLASS -- Time to work on third/final draft of proposal		Email: Third/final draft of proposal (abstract + entire research plan) + human subjects, resources/ environment & budget/budget justification, due to small group instructors by 5 pm
Th 10	Student presentations	Beard/All	Score student presentations
Tu 15	Student presentations	Beard/All	Score student presentations
Th 17	Student presentations	Beard/All	Score student presentations
Tu 22	Student presentations	Beard/All	Score student presentations
Th 24	Student presentations	Beard/All	Score student presentations
F 25	<i>Last day of UNC classes</i>	*All =	Instructors=Gammon, Heiss, VanRie, Daniels; TA=Beard