EPIDEMIOLOGY 726 - EPIDEMIOLOGIC RESEARCH METHODS
Spring 2017 Syllabus

INSTRUCTORS: *Office hours by appointment*	**Group Meeting Location**
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OBJECTIVES: The course is designed to integrate and apply the principles and methods learned in epidemiology courses to the design of epidemiologic studies. In EPID 725, students learned the structure of a National Institutes of Health (NIH) grant, the grant review process, and how to identify a research topic and develop study aims. In EPID 726 students develop the entire research proposal using NIH format. This course requires students to convey in a compelling manner the study's significance, innovation, study design, study implementation strategies, and the ethical conduct of research that will address the specific aims.

Attention to an array of substantive and methodological considerations is needed in order to propose an informative, scientifically justified, and realistic study, according to the standards applied in NIH peer review. Students can propose a new study or an ancillary study that complements an existing resources in a sophisticated way to address a novel question that was previously unanswered by the originally collected data.

COURSE STRUCTURE: The course alternates between "lectures" in the classroom and interactive "small group" sessions. The order of sessions is designed to follow the general sequence of a NIH R01 research grant proposal. Please be aware, however, that students 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, at times students will work on more than one section of the proposal simultaneously rather than in strict sequence. Modifications in a given section must be reconciled with other sections. Grant preparation is an iterative process. Ongoing revision is expected.

LECTURES: Lectures and panel discussions focus on critical issues students will confront during proposal development. Students should read assignments prior to the lectures and to participate in discussions.

SMALL GROUPS: Small group composition is based on research interests, as much as possible. The small groups provide an opportunity for students to peer review and critique the developing proposal with assistance from the instructor and other students. Group members become familiar with the proposals from their group, which facilitates shared learning and discussion of new issues with minimal review. Most small group sessions have an accompanying assignment (requiring students to write a new section of their proposal).

PEER-REVIEW: During the small group session, students peer review each grant section/assignment. Two reviewers are assigned per student principal investigator (one as primary reviewer and one as secondary reviewer). Peer review should focus on substance, methods, and clarity of each section. The reviewers are expected to prepare *brief* written comments on the assignment submitted by their assigned peer-applicant (bullet format). *Reviewers should focus on the most important issues, noting three positive and three negative issues about the assignment*. Reviewers should *not* give a detailed editorial review or provide suggestions for changes (i.e. reviewers should simply note that more or different information is needed, that more support is needed for a decision, or that a section is unclear).

Reviewers also present their comments orally in the small group session. The peer reviewers are responsible for identifying strengths and weaknesses in the written assignment/draft grant application. Reviewers should not pose questions directly to the grant writer or recommend solutions during the peer review session. Small group time is limited, consequently the review time for each assignment is by necessity short. Thus, peer review should be specific and brief to ensure fair time for all students.

The small group sessions that are designated as "Unresolved Issues" are in place to allow an open discussion forum for students to further discuss issues and pose questions to their group to help them resolve issues noted in prior peer reviews or issues they know will arise in future assignments.

During all 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).*

ASSIGNMENT FORMATTING AND SUBMISSION PROCESS
For all proposal drafts/assignments, use black Arial 11 font, margins of 0.5 all-around, and include references. All shared documents should be distributed as a *Word* file, not as a .pdf. Name your documents using the following convention: EPID726_Assn1_NAME.docx; where the student's last name replaces "NAME".

Send all assignments to entire small group by the due date through the *Forum* tab provided in Sakai. As noted above, **the circulating proposal document is cumulative**; thus, each time students share their proposal with the small group, the new section should be appear in its proper place and with the most up-to-date version of all the previous sections of the proposal included.

LATE POLICY: To give the reviewers sufficient time, students must submit assignments/draft proposals *to the entire small group (via Sakai) by 11 am* the day before the small group discussion (noted in the course schedule). Graded submissions that are late will be penalized 5% per day. While individual assignments are not graded by instructors, late submissions adversely impact preparatory time for peers in the small group. Students who repeatedly submit assignments or are not prepared for peer reviews late, without an excuse from the instructor, will be removed from the peer review small group schedule, assigned a grade of "Incomplete", and required to retake the class. ***Most funding agencies, including NIH, do not accept late proposals. Consequently, students are expected to comply with due dates and times in this grant writing course.***

COURSE MATERIALS: available on the course website at (http://sakai.unc.edu) under the following headings:

- **Syllabus:** 1) Syllabus, 2) Schedule for class meetings and assignments, 3) Assignment descriptions
- **Resources:** Examples of funded grant proposals written by course instructors, former students enrolled in this course, and other members of the department. Students may find it helpful to refer to grant examples frequently as the work on various sections of their own proposals. ***Example grants should only be used by enrolled students for reference. They should not be distributed, as they may include confidential material not provided in public documents.***
- **Forums:** A separate forum will be provided for each assignment and each small group. This forum should be used by students to submit assignments.

GRADING: Grades are determined by the small group instructor. We emphasize the quality of the final proposal, but consideration is also be given to the amount of progress made over the course of the semester.

10% First Draft of Proposal (Assignment 2)
20% Second Draft of Proposal (Assignment 5)
10% Peer Review of First Draft of Proposal (Assignment 6)
35% Final Research Proposal (Assignment 10)
15% Final Oral Presentation (Assignment 11)
10% Participation in Lectures, Small Group, and Peer Review

FINAL GRADE Guidelines:
H – Proposal is of sufficient quality to be submitted to NIH as an R01, R21, or R03 with minimal revision.
P - Proposal would require some additional work to submit for funding; but it is scientifically rigorous, generally well-written, and clear.
L – Proposal that falls below the standard above, or students with repeated poor performance on written assignments and/or chronically late submissions. Weak performance may require repeating the course.