EPI 998 / CPH 649: Special Topics in Epidemiology
Research Proposal Development

Spring 2015
2 credits

COURSE SYLLABUS

Course Description:
This course is designed to provide doctoral and other graduate and professional students with a practical experience writing a research grant proposal for submission to the National Institutes of Health (NIH). Students will learn how to formulate research questions, develop study aims, and build research study designs closely tied to analysis plans and research outcomes. Students will learn how to find and respond to various federal and non-federal funding mechanism opportunities. Students will participate in a mock NIH study section, during which they will learn the NIH peer review process and they will critique research grant proposals. Throughout the course, students will work interactively with faculty members who have successfully served as principal investigators and co-investigators of multiple federally-funded research proposals or contracts in different disciplines.

Prerequisites: None. A prior research methods course is recommended

Audience: Doctoral students. Other graduate and professional students with permission of the instructor.

Contact Instructor:
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Co-Instructors:

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Class time and location: Monday 1:00-2:50 PM

Office Hours: By appointment

ADA Policy

Students with disabilities who are in need of accommodations should contact the Student Disability Services office (see below). In order to be eligible for accommodations, the student is responsible for registering with this office and providing documentation of disability. The student must register and provide documentation well in advance of the semester for which the accommodation is needed (6 weeks is suggested). Once the request has been approved, an individualized accommodation plan will be formulated, and an official "Letter of Disability Accommodation" will be issued to the student. Instructors will not provide classroom accommodations without prior approval.

Student Disability Services
Bennett Hall, Room 6001 (402) 559-7276

Pat Oberlander
E-mail: poberlander@unmc.edu

Course Attendance: Each student is expected to attend one class session (1 hour forty minutes) per week.

Course Format: Lectures, class presentations, assignments

Requirements:

Assignments (50% of course grade). Students will complete a series of assignments leading to the final research grant proposal. The assignments will cover different aspects of research study design, planning, and analysis: (1) Developing testable hypotheses, (2) Developing study methodology, (3) Developing an analysis plan.

Completed Research Grant Proposal (20% of course grade): the final product of the course. The research grant proposal will be the foundation for submitting a grant proposal to an external funding agency, if students wish to pursue further work in their area of interest.

Peer Reviews (10% of course grade): Using a template distributed in class, each student will review research grant proposals of three other students. Each student will complete a primary review and two secondary reviews.

Presentation (15% of course grade): Students will present their research grant proposals before the study section. Guidelines will be given for presentations, which should be approximately 15 minutes in length.

Attendance, preparation, participation (5% of course grade)**:** Because approximately half the course time will be spent on discussions of research issues and students' independent work, attendance at all class meetings is expected except in the case of extenuating circumstances, such as illness, emergency, or attending a professional conference. The discussions require each student's adequate preparation, and thoughtful, courteous participation. Students will be expected to read the assigned materials in depth to participate fully in discussions. Students will earn one point for each of the following: participation in at least 80% of the lectures, completion of the assignments, proposal and peer review by the deadline, and active participation in discussions.

Course Website: http://my8.unmc.edu (use your Outlook user name and password)

Recommended Readings:

Gerin W, Kapelewski C, Itinger JB, Spruill, T. Writing the NIH Grant Proposal: A Step-by-Step Guide. Second Edition. SAGE Publications, 2010.

Hulley, Cummings, Browner, Grady, Newman. Designing Clinical Research (Fourth Edition). Lippincott Williams & Wilkins, 2013.

NIH grant writing tips sheets
http://grants.nih.gov/grants/grant_tips.htm

NIH/NIAID sample applications and summary statements:
http://www.niaid.nih.gov/researchfunding/grant/pages/appsamples.aspx

NIH peer review revealed (video):
http://public.csr.nih.gov/aboutcsr/contactcsr/pages/contactorvisitcsrpages/nih-grant-review-process-youtube-videos.aspx

COPH intranet; Repository of Funded Grant Applications

Other reading assignments will be accessible online at the course website.

Grading: Specific information about the grading criteria for each component will be distributed with the assignment. The relative weight of each course component is as follows:

50%	Homework Assignments
20%	Study Protocol
10%	Peer Review
15%	Presentation
5%	Attendance, Preparation, Participation

The grading scale will be:

Grade Point:	4.0	4.0	3.67	3.33	3.0	2.67	
Final Percentage:	100-98	97-93	92-90	89-88	87-83	82-80	
Grade:	A+	A	A-	B+	B	B-	
Grade Point:	2.33	2.0	1.67	1.33	1.0	0.67	0
Final Percentage:	79-78	77-73	72-70	69-68	67-63	62-60	<60
Grade:	C+	C	C-	D+	D	D-	F

Competencies: Upon completion of this course students will be able to:

- Synthesize and communicate information from the scientific literature and original ideas to develop a competitive grant proposal
- Demonstrate grant-writing skills
- Formulate research questions
- Select appropriate observational, interventional, or secondary (e.g., analytical) study designs to address specific research questions
- Identify and discuss advantages and limitations of study designs, including practical aspects of their use and trade-offs in particular studies
- Select appropriate analytical approaches to answer research questions
- Understand and apply principles for ethical study conduct and treatment of research participants
- Respond to grant proposal peer reviewers' comments
- Apply peer review system principles to critique grant applications

Academic integrity and professional conduct:
The University of Nebraska Medical Center has established a policy on academic integrity and professional conduct. This policy may be found in the UNMC Student Handbook. All graduate students are expected to adhere scrupulously to this policy. Cheating, academic misconduct, fabrication, and plagiarism are viewed as serious matters and will lead to disciplinary action as described in the UNMC Student Handbook under Procedural Rules Relating to Student Discipline. Additional materials related to Responsible Conduct in Research can be found in the UNMC Student Handbook.

Selected sections from the UNMC Student Handbook include:

Cheating: A general definition of cheating is the use or attempted use of unauthorized materials or information for an academic exercise. Examples of cheating include:

1. Using unauthorized materials such as books, notes, calculators or other aids during an examination or other academic exercises;
2. receiving unauthorized assistance from another person during an exam or exercise such as copying answers, receiving answer signals, conversation or having another person take an examination for you;
3. providing assistance to another person during an exam or exercise, such as allowing your answers to be copied, signaling answers or taking an exam for someone else;
4. obtaining answers and/or other information without authorization from someone who has previously taken an examination;
5. including all or a portion of previous work for another assignment without authorization

Academic misconduct: Academic misconduct is defined as the falsification of official documents and/or obtaining records, examinations or documents without authorization. Several examples of academic misconduct are:

1. the unauthorized acquisition of all or part of an unadministered test;
2. selling or otherwise distributing all of part of an unadministered test;
3. changing an answer or grade on an examination without authorization;
4. falsification of information on an official university document such as a grade report, transcript, an instructor's grade book or evaluation file or being an accessory to an act of such falsification;
5. forging the signature of an authorizing official on documents such as letters of permission, petitions, drop/add, transcripts, and/or other official documents;
6. unauthorized entry into a building, office, file or computer data base to view, alter or acquire documents.

Plagiarism: Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, i.e. an appropriate attribution or citation. Some examples are:

1. In the methods section of a thesis, a graduate student describes a procedure used in research for the thesis. The procedure was developed by a fellow graduate student in the laboratory of their major professor; however, neither the student who developed this procedure nor the major professor was given credit in the thesis. This implies that the author of these had himself developed the procedure.
2. In the background section of a thesis, a graduate student quotes verbatim the results of a previous investigator's work but fails to credit the individual through citation. The work is recent and thus cannot be considered common knowledge.

Course Outline

This schedule may change as the semester progresses. Changes will be posted via *Blackboard*.

Week	Date	Lecture Topic	Instructor	Students' Assignments Due	Reading assignments
1	01/12	Course overview; fatal flaws of grant proposals; getting started: how to find a gap in current scientific knowledge and choosing your team	Baccaglini	---	---
2	01/19	No class. Martin Luther King's day	---	---	---
3	01/26	Overview of funding sources & mechanisms (PCORI, NIH, RWJ, etc.), grants.gov, NIH Reporter, components of an NIH application, overview of NIH review process	Siahpush	*[Identify gap in scientific knowledge]*	WNG: Ch. 3, Ch. 4 (pp. 54-55), Ch. 5 (pp. 61-73), Ch. 9
4	02/02	Formulating a research hypothesis, selecting a study design and statistical methods	Haynatzki	*[Identify gap in scientific knowledge]*	DCR Ch.2
5	02/09	Abstract and Specific Aims	Siahpush	Submit Research Question(s)	COPH intranet
6	02/16	Significance and Innovation	Siahpush	Submit Specific Aims page	COPH intranet
7	02/23	Research Approach & Timeline – Part I	Wilson	Submit Significance and Innovation Section	WNG: Ch. 5 (pp. 87-108). DCR Ch. 7-8
8	03/02	Research Approach & Timeline – Part II	Wilson	*[Write draft Research Approach section]*	WNG: Ch. 5 (pp. 87-108). DCR Ch. 10-11
9	03/09	Biostatistical aspects of grant proposals	Haynatzki	Submit Research Approach Section	DCR Ch. 5
10	03/16	Completing a Budget, Biosketch and Other NIH Sections (Summary, Narrative, Facilities, Justification)	LeVan	Submit research proposal to NIH review panel (excluding sections listed below)	WNG: Ch.7 pp. 153-170
11	03/23	No class. Spring break	---	---	---
12	03/30	Guidelines for NIH peer reviewers. Response to NIH critiques.	Wyatt	Submit summary, narrative, facilities *[Review proposals]*	NIH peer review video
13	04/06	Human subjects protection, vertebrate animals, sample size and power calculations	Haynatzki	Submit NIH peer review	DCR Ch. 5-6 DCR Ch. 14
14	04/13	Alternatives to NIH (RWJ, Russell Sage, Commonwealth, CDC, etc.)	Wilson	Submit Human Subjects Protection Section & Biosketch	NIAID sample applications
15	04/20	NIH and PCORI research grant applications	Soliman, Islam	Submit budget and budget justification	TBA
16	04/27	Mock NIH Peer Review Panel 1 - Student peer review & discussion of students' proposals (not graded)	Wyatt	Submit revised peer review	Read proposals
17	05/04	Mock NIH Peer Review Panel 2 - Student peer review & discussion of students' proposals (not graded)	Wyatt	Submit revised peer review	Read proposals

WNG: *Writing the NIH Grant Proposal* DCR: *Designing Clinical Research*