Syllabus for BIOSTAT 599  
Planning and Funding of Clinical Research  

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COURSE OBJECTIVES:  
• Understand the structure/function of NIH  
• Understand the NIH review process  
• Understand organization of NIH grant application  
• Develop grant-writing skills  
• Understand how to write good specific aims, background & methods sections of proposals (now identified as significance, innovation and approach)  
• Write an R01-type or K-type proposal  
• Serve on mock study section & review colleagues proposals  
• Develop strategies for successful revision of reviewed proposals  
• Understand post-award activities – research administration, Manual of Operations/Procedures, data forms and management, regulatory reporting, IRB applications and review  

COURSE ORGANIZATION:  
The schedule below is a rough goal for the timing of topics in this course. It is subject to adjustment according to the needs of the class.  

TEXTBOOKS:  
No required textbook for the class.  

OTHER REFERENCES:  
Liane Reif-Lehrer (2005), Grant Application Writer’s Handbook, Boston: Jones and Barlett. Relevant chapters will be available on CTOOLS.
Course Grade:
Your course grade will be based on class attendance and participation, and completion and submission of all homework assignments ON TIME.

Projected Course Timeline

Session 1:
**July 15** (Thurs) 8:30 – 10:20am and **July 16** (Fri) 8:30 – 10:20am (**4 hours**)
Lectures/Discussions:
Introduction: syllabus, course objectives, course structure
NIH structure/function, review process
NIH grant application - overview
Description of RO1 proposals
Discussion of research questions
Development of specific aims

Readings: from Grant Application Writer’s Handbook – available on Course Tools.
Understanding the NIH Review Process, pp 28-50
Parts of the Grant Application, pp 55-117

**Homework 1: due Monday August 16**
Develop the research question to be pursued in your research proposal and prepare a brief description of your research question, together with draft specific aims.
Send via email to instructors who will select those for discussion at Aug 22 meeting.

Session 2:
**August 22** (Sun) 8 – 9:50am (**2 hours**)
Lectures/Discussions:
Group discussions of selected research questions/specific aims from Homework 1

**Homework 2: due Thursday September 23**
Revise, expand and refine your research question and specific aims, draft Research Methods (bullet points only)

Session 3:
**September 23** (Thurs) 8:30am – 12:20pm (**4 hours**)
Lectures/Discussions:
Organization of proposal
Significance, Background, Preliminary Studies and Methods sections (now identified as significance, innovation and approach)
Example proposals for discussion
Consultations with instructors on research ideas (schedule in Course Tools)
**Homework 3: due Monday October 11**
Draft Significance, Background, Preliminary Studies and Methods sections (now identified as significance, innovation and approach) of your proposal

**Session 4:**
**October 16 (Sat) 8:30am – 12:20pm (4 hours)**
Lectures/Discussions:
Proposal Resources and Facilities sections, Project Feasibility
Budget – overview
Consultations with instructors on draft proposals (schedule in Course Tools)

Readings: from Grant Application Writer’s Handbook – available on Course Tools.
Polishing the pre-final draft, pp 160-169
Information about NIH, pp 216-232

**Homework 4: due Monday November 15**
Draft remainder of proposal
Identify appropriate NIH Institute/Center and Study Section for your proposal and possible reviewers; draft cover letter

**Session 5:**
**November 18 (Thurs) 8:30 – 10:20am, November 21 (Sun) 10am – 1:50pm (6 hours)**
Lectures/Discussions:
Organize study sections for mock review of class proposals
Proposal refinement
Consultations with instructors on proposals (schedule in Course Tools)

**Homework 5: due Monday December 13**
Final Proposals

**Session 6:**
**December 18 (Sat) 8:30am – 12:20pm (4 hours)**
Lectures/Discussions:
Reviewing proposals, preparing written critiques
Distribute proposals to primary and secondary reviewers

**Homework 6: due Monday January 10**
Prepare written critiques of assigned proposals
Prepare to discuss reviewed proposals at MOCK Study Session

**Session 7:**
**January 13-16 (Thurs – Sun) (10 hours)**
Mock study section meeting – reviewed proposals presented and discussed
Lectures/Discussions: Preparing Summary Statements
Readings: from Grant Application Writer’s Handbook – available on Course Tools.
Summary statements, rebuttals and revisions, pp 172-178

**Homework 7: due Monday February 14**
Primary/Secondary reviewers prepare summary statements (‘pink sheets’) for reviewed proposals

**Session 8:**
*February 17-20 (Thurs – Sun) (4 hours)*
Lectures/Discussions:
Responding to critiques – proposal revision
Institutional resources (administrative support) and navigating research grant offices

**Homework 8: due Friday March 11**
Revise proposal based on summary statements

**Session 9:**
*March 17-20 (Thurs – Sun) (8 hours)*
Lectures/Discussions:
Discussion of responses to critiques
Understanding post-award activities
Development of Manual of Operations/Procedures
Data collection/report forms, data management
Regulatory reporting (IND, SAEs)
IRB applications and review