

Syllabus for BIOSTAT 599
Planning and Funding of Clinical Research

JULY 2010

Instructors:

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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