CLRES 2076: Introduction to Grant Writing Mondays and Wednesdays Date, Location, and Time 3/26/18 - 4/25/18; Parkvale Room 219: 3:00-5:00 PM Institute for Clinical Research Education, 200 Meyran Avenue

Course Instructor: Bruce L. Rollman, MD, MPH Suite 600, 230 McKee Place rollmanbl@upmc.edu

Overview and Objectives

Obtaining external peer-reviewed grant support is one of the most daunting yet critical determinants to academic and career success. Through select readings and podcasts, writing a draft grant application, and class discussions led by a long-time NIH-funded clinical investigator, this course will provide CEED trainees, clinical fellows, post-doctoral students, and junior faculty without any prior grant writing experience with useful knowledge, insights, and skills in the grant writing process to improve their chances of later funding and subsequent career success.

Course Requirements

- 1. Completion of required readings, podcasts, and web video *prior* to each session.
- 2. Submission of a draft grant application requesting funds from a University-approved pilot program (http://www.ctsi.pitt.edu/planpilot.shtml) (40% of grade)
- 3. Class attendance and participation (60% of grade).
- Schedule a 30-minute meeting with Dr. Rollman April 5-24 to discuss your draft grant proposal and future career plans in his office (Suite 600, 230 McKee Place) To schedule, call or email Monica Kosmer, Administrative Assistant: 412-692-2659; kosmermh@upmc.edu).

Textbook

Eisenberg, MJ. The Physician Scientist's Career Guide. Springer 2011.

Key Web Resources

New and Early Stage Investigator Policies http://grants.nih.gov/grants/new_investigators/index.htm

Links to continually updated information new investigators need to know about the overall and institute-specific NIH application process all in one place.

All About Grants Podcasts - <u>https://grants.nih.gov/news/virtual-learning/podcasts.htm</u> The Office of Extramural Research (OER) presents conversations with NIH staff members designed to provide investigators at all career stages with easy-to-understand insights on a wide variety of grant topics.

Tips and Advice for NIH Grant Proposal Submissions - <u>http://nihgrants.blogspot.com/</u> Information, tips, tricks, and useful links to help navigate the NIH grant proposal process.

4Researchers.org - <u>http://www.4researchers.org/</u> A searchable collection of short videos containing practical advice from clinical investigators. NIH Extramural Nexus. http://nexus.od.nih.gov/all/category/blog/

Highly recommend you subscribe to "Open Mike" from Dr. Michael Lauer, Deputy Director for Extramural Research, to stay on top of the latest developments in NIH grant policy.

Academic Integrity

Students in this course will be expected to comply with the <u>University of Pittsburgh's Policy on</u> <u>Academic Integrity (http://www.provost.pitt.edu/info/ai1.html).</u> Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity.

Disabilities

If you have a disability that requires special testing accommodations or other classroom modifications, you need to notify both Dr. Rollman and the <u>Disability Resources and Services</u> (http://www.studentaffairs.pitt.edu/drsservices) no later than the second week of the term. You may be asked to provide documentation of your disability to determine the appropriateness of accommodations. To notify Disability Resources and Services, call 648-7890 (Voice or TTD) to schedule an appointment. The Office is located in 216 William Pitt Union.

Course Grading Scale

This course will be graded on a pass/fail scale. To pass the class, students will need to attend \geq 75% of classes and submit a satisfactory fourth and final draft Specific Aims for review by <u>May 3</u>, 1 week after the date of the final class.

Incomplete grades

Students who are unable to complete the course for any reason must contact Dr. Rollman as soon as possible to discuss grades and remediation [course reasons ("I" incomplete), extenuating personal reasons ("G" incomplete), withdrawal ("W")]. Students will have one calendar year from the start of the course to complete the course requirements, otherwise an "I" or "G" grade will remain on their transcript.

Session 1: Introduction to Grant Writing Monday, March 26, 2018; 1:00-3:00 PM

Learning Objectives:

- 1. Articulate the importance of obtaining peer-reviewed grant support to one's career.
- 2. Explain the "10,000 Rule".
- 3. Describe the types of career-development awards available to new and young investigators.
- 4. Critically evaluate a request for applications (RFA).

Topics:

- 1. Course overview.
- 2. What grants are and why they are important.
- 3. Where to apply for grants.
- 4. Grants types for new and junior investigators.

Competencies

Methodology: Identify potential funding sources for research projects.

Required reading before the session:

Eisenberg textbook; Chapter 11, Grants

Required listening/viewing before the session:

"10,000 Hour Rule" YouTube - http://www.youtube.com/watch?v=Kq2n1Jlx5P0

5,000 Hours of Effort *4researchers.org* - <u>http://www.4researchers.org/articles/2397</u>

Malcolm Gladwell's 10 Rules for Success -https://www.youtube.com/watch?v=iNiJEsb1PMw

NIH Grant Application Basics: http://grants.nih.gov/grants/grant_basics.htm

"NIH Early Career Funding" 4researchers.org - http://www.4researchers.org/articles/6862

"Grant Writing for New Investigators" - *All About Grants* podcast http://grants.nih.gov/podcasts/All_About_Grants/episodes/Grant_Writing_April_2010.mp3

In-class exercise:

Prior to class, explore the Office of Research for the Health Sciences Database and CTSI websites for pilot and other programs that could support your research (http://oorhs.pitt.edu/research-funding/funding-opportunities and

http://www.ctsi.pitt.edu/funding-pilot-foa.html). Bring 1-2 funding opportunities you find on these or other websites to class and be prepared to discuss details of the application(s) and why you selected it.

Session 2: Choosing a Research Question Wednesday, March 28, 2018; 1:00-3:00 PM

Learning Objectives:

- 1. Discuss various strategic issues involved with selecting a research question.
- 2. Describe how new scientific ideas develop.
- 3. Use the Internet to conduct "due diligence" on the originality of ones ideas.
- 4. Explain several key issues when deciding among potential funding agences.

Topics:

- 1. How to identify ambitious, feasible, and "fundable" project ideas.
- 2. What is project "due diligence"
- 3. How to conduct "due diligence" on one's own ideas for projects

Competencies

Problem Formulation: Propose significant and novel empirical, testable, hypothesis-driven research questions using, where appropriate, different disciplines and community engagement.

Problem Formulation: Conduct comprehensive literature reviews from appropriate sources across disciplines

Methodology: Identify potential funding sources for research projects.

Required reading before the session:

Eisenberg textbook; Chapter 8, Research

Chapter 12, Grantsmanship

Required listening/viewing before the session:

Where good ideas come from - http://www.youtube.com/watch?v=NugRZGDbPFU

https://www.ted.com/talks/steven_johnson_where_good_ideas_come_from

Walter Isaacson on the traits of technology's "Innovators" - <u>https://www.youtube.com/watch?v=qOXhSRWQyyw</u>

Mentorship is the key to success - http://www.4researchers.org/articles/10670

Plan Your Application - https://grants.nih.gov/grants/planning_application.htm

Research Online Reporting Tools (NIH RePorter): http://projectreporter.nih.gov/reporter.cfm

Clinicaltrials.gov: http://clinicaltrials.gov/

Research Career Development Awards (identify a potential K-award mechanism for you): <u>https://researchtraining.nih.gov/programs/career-development</u>

Required written assignment. Send to Dr. Rollman by 9 AM, Monday April 2:

E-mail Dr. Rollman one or two ideas for projects that you might pursue pilot funding for (rollmanbl@upmc.edu). Each idea should be 2-3 paragraphs long that: (1) begins with 1-2 sentences describing the background of the problem, (2) includes a testable research hypothesis; and (3) can be completed in under 24-months.

In-class exercise:

In class, Dr. Rollman will review the ideas submitted in writing by students and demonstrate on-line tools and strategies they can use to conduct "due diligence" on their own ideas.

Learning Objectives:

- 1. Explain why a well-written Specific Aims section is critical to funding success.
- 2. Describe the structure and elements of a well-crafted Specific Aims document.
- 3. Identify common flaws investigators make drafting their Specific Aims section.

Topics:

- 1. The purpose of the Specific Aims section.
- 2. Why the Specific Aims section is so critical to funding success.
- 3. Components of a compelling Specific Aims section.

Competencies

Problem Formulation: Critically review published studies that use various research methodologies and identify possible sources of bias and potential health disparities therein

Written Communication: Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism.

Required reading before the session:

Eisenberg textbook; Chapter 9, Writing

What should I write first? - Tips and Advice for NIH Grant Proposal *Submissions* http://nihgrants.blogspot.com/2010/08/what-should-i-write-first.html

Required listening/viewing before the session:

"Telling your Story" - All About Grants podcast http://grants.nih.gov/podcasts/All_About_Grants/episodes/Telling_Story_March_2011.mp3

"NIH Tips for Applicants" - https://www.youtube.com/watch?v=IAOGtr0pM6Q&t=14s

"Make it Crystal Clear" - 4researchers.org - http://www.4researchers.org/articles/4580

"Send us a Concept Paper First" 4researchers.org - http://www.4researchers.org/articles/3687

"Common Challenges and Problems in Constructing Specific Aims: Preparing your First NIH Grant" - <u>https://www.youtube.com/watch?v=1Cj_YKrQzpE</u>

Rigor and Reproducibility in NIH Applications: https://grants.nih.gov/reproducibility/index.htm

In-class exercise:

We will distribute the Specific Aims sections from several NIH grant applications and highlight the structure and elements of a well-crafted draft.

Required written assignment, send to Dr. Rollman by 6 PM Sunday April 8:

E-mail Dr. Rollman a 1-2 page draft Specific Aims section for your pilot project. Describe the background of the problem, two or three specific aims, and include a "testable" primary hypothesis and at least one testable secondary hypothesis. Dr. Rollman will return them to you with feedback at our Session 4 class.

Session 4: Significance, Innovation, and Approach Wednesday, April 4, 2018; 1:00-3:00 PM

Learning Objectives:

- 1. Describe the Significance, Innovation, and Approach sections of a grant application.
- 2. Explain the importance of storytelling to building compelling grant applications.
- 3. List the key elements of an exciting "fundable" Approach section.

Topics:

- 1. The purposes and elements of the Significance, Innovation, and Approach sections.
- 2. Storytelling in grant applications.
- 3. Approach section do and don'ts.

Competencies

Written Communication: Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism and questions.

Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research including: data collection, sharing, and protection; and reporting of findings.

Required reading before the session:

Students will read the Significance, Innovation, and Approach sections from several proposals that will be distributed prior to class.

Required listening/viewing before the session:

"Including All in Clinical Research" - *All About Grants* podcast http://grants.nih.gov/podcasts/All_About_Grants/episodes/Telling_Story_March_2011.mp3

"Write Your Research Plan" - *NIAID Website* https://www.niaid.nih.gov/grants-contracts/write-research-plan#A18

"Write Your Application" Scroll-down to "What Peer Reviewers Look For" on *NIH Office fo Extramural Health Website* -

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-yourapplication.htm#What Peer Reviewers Look For

In-class exercise:

We will review the Significance, Innovation, and Approach sections from several proposals distributed prior to class.

Rollman will return your writing assignment to you with feedback. Please bring a revised draft to our April 9 Session 5 class.

A Learning Objectives:

- 1. Explain the difference between a CV and a Biosketch.
- 2. List the elements of an NIH Biosketch
- 3. Draft a basic biosketch personal statement.

Topics:

- 1. Grant timelines.
- 2. The 2018 NIH Biosketch.
- 3. The biosketch personal statement.
- 4. Letters of support.
- 5. Feedback on students' draft Specific Aims document.

Competencies

Written Communication: Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism and questions.

Multidisciplinary Teamwork: Engage in self-assessment, recognizing and addressing strengths and weaknesses in their research skills.

Management: Demonstrate behaviors needed to be an effective project manager including: oversight of fiscal regulations; recruitment; human resource management; and quality assurance.

Required reading/listening before the session:

Biosketch format pages, instructions, and samples https://grants.nih.gov/grants/forms/biosketch.htm

Biosketch advice from the NIH blog http://nihgrants.blogspot.com/search/label/Biosketch%20Personal%20Statement

The Worst Personal Statement Ever - Tips and Advice for NIH Grant Proposal Submissions http://nihgrants.blogspot.com/2012/06/worst-personal-statement-ever.html

How Collaborative Genius Drives Innovation: <u>https://www.youtube.com/watch?v=1wRU_STOg_c</u>

"Assembling the Right Team" - All About Grants podcast: http://grants.nih.gov/podcasts/All_About_Grants/episodes/Personnel_Sept_2011.mp3

In-class exercise:

Together, we will review together several NIH Biosketches that will be distributed in class and the draft Specific Aims students submitted at the end of our last class.

Required written assignment for submission in Session 6:

Create your Biosketch and personal statement using the fillable PHS 398 forms on the NIH website https://grants.nih.gov/grants/forms/biosketch.htm

Session 6: *Budgets and Letters of Support* Monday, April 16, 2018; 1:00-3:00 PM

Learning Objectives:

- 1. Describe how the NIH funds projects.
- 2. Explain the basics of grant budgeting.
- 3. List the 7 elements of a budget justification section.
- 4. Describe when to include a "letter of support" and the elements of a strong letter.

Topics:

- 1. Grant budgets, what it is and where the money goes.
- 2. What spending is allowed by NIH.
- 3. How to write a strong budget justification.

Competencies

Written Communication: Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism and questions.

Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research including: data collection, data sharing, data protection, and reporting of findings.

Multidisciplinary Teamwork: Describe the functions and roles of multiple disciplines with which they interact.

Management: Demonstrate behaviors needed to be an effective project manager including: oversight of fiscal regulations; recruitment; human resource management; and quality assurance.

Required reading and listening before the session:

Eisenberg textbook; Chapter 14, Managing your Team, Time, and Money.

Develop your Budget - <u>http://grants.nih.gov/grants/developing_budget.htm</u>

Plan your Budget and Personnel -

https://www.niaid.nih.gov/grants-contracts/plan-budget-personnel

"Design First, Budget Later" 4researchers.org - http://www.4researchers.org/articles/3677

"Why are Budgets Cut" - *All About Grants* podcast: http://grants.nih.gov/podcasts/All_About_Grants/episodes/Budget_cuts_June_2011.mp3

In-class exercise:

We will review and discuss the Budget Justification and Letters of Support from several recent NIH grants.

Required written assignment:

Submit your Biosketch by the end of class.

Session 7: The NIH Grant Review Process Monday, April 23, 2018; 1:00-3:00 PM

Learning Objectives:

- 1. Describe the basics of the NIH peer-review process.
- 2. Explain what NIH reviewers look for when reviewing grant applications.
- 3. Identify the components of the Summary Statement.

Topics:

- 1. What goes on in a study section.
- 2. What is a Summary Statement and how to interpret it.
- 3. Reading the tea leaves, or "what are the reviewers trying to tell me".

Competencies

Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research including: data collection, data sharing, data protection, and reporting of findings.

Multidisciplinary Teamwork: Engage in self-assessment, recognizing and addressing strengths and weaknesses in their research skills.

Required reading before the session:

Eisenberg textbook; Chapter 13, Peer Review of Grant Applications.

- NIH Peer Review Process Revealed https://www.youtube.com/watch?v=fBDxI6l4dOA&feature=youtu.be
- NIH Peer Review https://grants.nih.gov/grants/peer-review.htm#scoring2

NIH Review Criteria at a Glance

https://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a_glance.pdf

Required listening/viewing before the session:

"The Ins and Outs of a Study Section Meeting", "Scoring Your Application", and "Summary Statement Basics" *All About Grants* podcasts

In-class exercise:

We will review the summary statements from several NIH grants that will be distributed in class.

Required written assignment to complete:

By 10:00 PM on Sunday April 22, e-mail Dr. Rollman a revised 1-2 page third draft Specific Aims section for your pilot project that includes the background of the problem, two or three specific aims, a "testable" primary hypothesis and at least one secondary hypothesis.

Dr. Rollman will review your submission and "assign" a primary and secondary reviewer to each draft proposal in Session 7. Each student should be prepared to provide a 3-5 minute oral and written critique on their assigned grants during our Session 8 class and submit their written critique to Dr. Rollman and to the student applicant.

Session 8: *Reviews and Wrap-Ups* Wednesday, April 25, 2018; 1:00-3:00 PM

Learning Objectives:

- 1. Provide team feedback on a Specific Aims document.
- 2. Describe some of the rewards and challenges of a clinician-investigator career.

Topics:

- 1. Mini-grant reviews.
- 2. Class summary.

Competencies

Problem Formulation: Propose significant and novel empirical, testable, hypothesis-driven research questions using, where appropriate, different disciplines and community engagement

Written Communication: Prepare critiques of written presentations following the appropriate guidelines (e.g., NIH).

Written Communication: Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism and questions.

Multidisciplinary Teamwork: Engage in self-assessment, recognizing and addressing strengths and weaknesses in their research skills.

Required reading before the session:

Read your assigned Specific Aims documents.

"Bad Reviews" 4researchers.org - http://www.4researchers.org/articles/2175/919

"Options If Your application Isn't Funded" – https://www.niaid.nih.gov/grants-contracts/options-if-application-not-funded

Recommended reading/listening:

Eisenberg textbook; Chapter 18, Balancing Research Clinical Activities, and Family Life.

Randy Pausch Lecture on Time Management – YouTube or podcast:

https://www.youtube.com/watch?v=oTugjssqOT0 or

https://itunes.apple.com/us/itunes-u/randy-pausch/id498300234?mt=10

https://www.youtube.com/watch?v=VUk6LXRZMMk

In-class exercise:

We will review and critique the Specific Aims sections submitted earlier. Be prepared to provide a 3-5 minute oral critique on your assigned grants.

Required written assignment to complete before the session:

By **May 1**, send Dr. Rollman a satisfactory revised fourth draft Specific Aims that is responsive to the peer-review critiques discussed in Session 8 (see Course Grading Scale; p. 2).