Welcome



OFFICE OF RESEARCH AND SPONSORED PROGRAMS (ORSP)

628 SOUTH HIGH STREET (FILANO HALL), SECOND FLOOR (610) 436-3557

HTTP://WWW.WCUPA.EDU/RESEARCH
RESEARCH@WCUPA.EDU

NIH 101: Proposal Development Workshop

- Thursday, November 17th
- Office of Research and Sponsored Programs (ORSP)
- www.wcupa.edu/research
- SharePoint site:
 https://sharepoint.wcupa.edu/vp/Advancement/SponResearch/default.aspx
- Laura Vassallo (<u>Ivassallo@wcupa.edu</u>) 610-430-5606

Overview of Topics Covered

- The Role of ORSP
- Very quick overview of NIH's organizational structure
- R15 and R03 Overview
- Required Sections of a typical NIH proposal
- How to create the budget
- Working with the Program Manager
- The approval process and how the PI and ORSP work together to ensure a timely submission
- NIH Review Criteria and Policy
- Questions

The Role of ORSP

- First and foremost, we are a customer service organization
- We are here to support you!
- Function differently than research offices at Research Intensive Universities (we are not just rubber stampers)
- Assist in <u>all</u> stages of the proposal and budget development and process, as well as all post-award activities
- Facilitate Contact with Program Manager
- Review and Summarize Funding Opportunity Notices
- Assemble application in eRa Commons (NIH's online submission tool)
- Submit application to the NIH
- Ensure an error-free submission

National Institute**S** of Health (IC's) http://www.nih.gov/icd/

Each Institute/Center (IC) has a different:

- mission & priorities
- budget
- funding strategy





NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Funding Announcements

Type of Funding Opps	Description
Parent Announcements	 Uses Standard Receipt Dates (Feb, Oct, June) By activity code (R01, R03, R15, R21 etc) For "investigator initiated" or "unsolicited" research ideas Some ICs may not participate in all parent announcements. (Check the funding announcement) Research must align with sponsoring IC mission and goals
Requests for Applications (RFAs)	 Solicit applications in a well-defined scientific area to accomplish specific program objectives Indicate the amount of set-aside funds and anticipated number of awards Often single receipt Dates

	R01	R03	R21	R15
Purpose	discrete, specified, circumscribed research projects	small research projects, including pilot and feasibility studies; secondary analysis of existing data; development of research methodology and new technology	exploratory and developmental research projects in early and conceptual stages; some risk but may lead to breakthrough in field or other methods or technical developments	Small scale research projects that expose students to research and strengthen the institution research environment; US institution that does not receive significant NIH Funding
Budget	As appropriate	\$50K/Year	\$275K entire	\$300K entire
Project Period	5 years	2 years	2 years	3 years

The AREA R15 Basics:

Program Announcement: PA-16-200

Goals of the Program

- Support meritorious research
- Expose students to research
- Strengthen the research environment of the institution

Grant Objectives by Institutes and Centers:

http://grants.nih.gov/grants/funding/area grant objectives.htm

Funding Opportunity Purpose: to stimulate research in educational institutions, that have not been major recipients of NIH support. AREA grants create opportunities for <u>scientists and institutions, otherwise unlikely to participate extensively in NIH research programs,</u> to contribute to the Nation's biomedical and behavioral research effort. AREA grants are intended to support small-scale research projects proposed by faculty members of eligible, domestic institutions.

Standard application deadlines

February 25, June 25, and October 25

WCU and the R15

Vanessa Johnson and Susan Gans, Psychology Department*

- "Whole Family Biopsychology as a Marker for Adjustment"
- Funded August 2010; \$215,400 over three years
- Eunice Kennedy Shriver National Institute of Child Health and Human Development

Liz Grillo, Communication and Sciences Disorders*

- "Effectiveness of Telepractice by Smartphone App Technology in Preventing Voice Problems"
- Funded September 2015; \$410,260 over three years
- National Institute on Deafness and Other Communication Disorders

Both of these funded grants were re-submissions of initially declined proposals.

NIH Small Grant Program (R03): PA-16-162

The R03 grant mechanism will support small research projects that can be carried out in a short period of time with limited resources.

Grant Objectives by Institutes and Centers:

R03 contacts and research priorities of participating institutes

Application Characteristics

- You may request a project period of up to two years and a budget for direct costs of up to two \$25,000 modules or \$50,000 per year.
- No preliminary data are required but may be included if available.
- The Research Strategy may not exceed 6 pages.

Scope

- Pilot or feasibility studies
- Secondary analysis of existing data
- Small, self-contained research projects
- Development of research methodology
- Development of new research technology

First Steps of proposal development

- Contact ORSP
 - http://wcupa.edu/research/contactInfo.aspx
- Notify Dean/Chair of your intent to apply for a grant
 - Often just a simple e-mail informing your Dean/Chair of you intention to apply, and the approximate timeframe.

Contact Program Officer

- Every institute at the NIH that supports an RO3 and/or R15 has a designated program
 officer for these mechanisms.
- Rely on your program officer for advice on grant applications and the specific institute's perspective on your research area.
- Contact ORSP if you need help identifying the correct PO for your application.

<u>Take Home</u>: The 100 Cardinal Rules for Writing an NIH Grant Application*

- Rule #1: Talk with your NIH Program Director before preparing your application
- •
- •
- •
- Rule #100: Talk with your NIH Program Director before preparing your application

*if you want to succeed...

From: NIH Grant Writing Workshop, John D. Porter, Ph.D. Program Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health



Contacting a Program Officer, Why?

- Program staff are your primary source of information for scientific, funding and programmatic matters, and they can advise you regarding:
 - A directorate's potential enthusiasm about your research area
 - Potential application topics
 - The appropriateness of your research for the program.
 - Topics of interest and new scientific directions
 - Additional information about initiatives that may not be listed on the funding announcement.

And how....

- Write up your Specific Aims. Using accessible language with a minimum of specialized terminology, describe your project in concise, concrete terms. List your main objective(s), methods, and expected outcomes. Stress the project's uniqueness and how the outcome(s) will address an important problem or contribute to the field.
- **Start with an e-mail.** In your pre-abstract, indicate why you think your project will achieve the grant program's objectives. End by asking if your work is the kind the program might consider funding. You should get a response within a day or two—study it for tone and nuance as well as its direct message.
- Make (or request) the call. Once there has been an exchange of e-mails, you have a
 relatively easy way to begin the conversation

Required Sections of the NIH proposal and page limits.

- Cover Letter (1 Page)
- Project Narrative (1-3 sentences)
- Project Summary (30 lines of text)
- Specific Aims (1 page)
- Research Strategy (Significance, Innovation, Approach)
 - 12 pages for R15
 - 6 pages for R03
- References Cited (no page limit)
- Budget
- Budget Justification (no limit)
- Facilities and Other Resources (no limit)
- Biographical Sketch (five pages)

Additional Resources

Prepare Proposal page of ORSP
Web Site

Guidance for each required Section of an NIH proposal

NIH Learning Community on ORSP SharePoint Site

Academic Writing vs Grant writing: two very different approaches

Academic Writing

- Work you have done
- Impersonal and dispassionate
- Verbosity Rewarded
- "insider Jargon"
- Reader wants to read and is already interested in your topic

Grant Writing

- Work you will do
- Persuasive and Passionate (sell your idea!)
- Brevity Rewarded (fewer words the better)
- Accessible Language
- Need to gain and keep reviewers interest (make it a good read)

Passive vs. Active Voice

Passive Voice

- It has been demonstrated by research that...
- The SAP program is being implemented by our department
- Following the administration of the survey, data will be analyzed
- It is anticipated that completion of the program will result in enhanced student scores

Active Voice

- Research clearly shows...
- Our department launched SAP this year...
- After administration of the survey, we will analyze the data
- At least 90% of the program participants will see an increase in their GPA

West Chester University Office of esearch and Sponsored Programs

Specific Aims Most important part of the application

Provides an overview of the entire project

▶List succinctly the specific objectives (aims) of the research proposed

- To test a stated hypothesis
- create a novel design
- solve a specific problem
- challenge an existing paradigm
- address a critical barrier
- develop a new technology

Keep in mind overall goal (NIH mission) should be to

- ✓ enhance health,
- ✓ lengthen life, and
- ✓ reduce illness and disability.
- Explain why this is a problem: what is the gap in the knowledge? Why is this a critical gap to fill?
- > Specify its innovation and contribution to the IC's mission, use specific terms from IC's website
- > State Concisely the goals of the proposed research
- > Summarize the expected outcomes
- > Describe the impact that the results of the proposed research will have on the disciplines involved.

After reading your specific aims:

Reviewers have to like your idea by the time they finish reading this page.

It should have persuaded reviewers that this project is important, that you are the right team to do it, and that it will advance the state of the science.

Significance

- Why is this study important?
- > How will your findings change science or medicine?
- > Examples:
 - > lives will be saved or quality of life improved (state how),
 - Health problems addressed at early stages or with new technology
 - New approaches to a known problem
- > 1 page may be sufficient.
- > Start with enough background information to support the conclusion that the study is important.

Innovation: Tips and Guidelines

- Mark the section clearly as Innovation (don't make the reviewer guess)
- One paragraph generally sufficient, probably not more than two
- Emphasize any innovative approach you are using:
- > why is your approach better than what has been done before;
- > what makes it novel and different?
- Innovative methods, innovative equipment, or an innovative way of looking at a problem can be emphasized.

General guidelines: Approach

- Should be longest section of proposal by far
- •Outline experiments in enough detail to be understood by an expert investigator who may not work directly in your area of the field.
- •Clear outlining and spaces in the application are essential! Reviewers need spaces. Here are some things to bear in mind:
- •The reviewers of your grant may be reading it at 2 AM after working all day. They will be grumpy. Grumpy people like spaces and clarity!
- •Diagrams and figures are very, very helpful. Figures help break up the page and maintain interest in the application.

General guidelines: Approach (con't)

- Summarizing at the end of sections is often helpful:
- "The experiments described above are an essential component of our plans to develop a vaccine to elicit broadly-neutralizing antibodies. These experiments will allow us to choose the best combination of immunogens to move forward with, thus setting the stage for animal inoculations described in Aim 2 below."

Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

Put headings in for Potential problems and alternative strategies after the approach section

- •To increase the confidence of the reviewer in your plan, you must acknowledge alternative ways of testing your hypothesis, without the reviewer thinking that these are better than your primary methods.
- •Include major alternatives, but does not need to be comprehensive

Overall Organization of Research Strategy

Option 1:

- Significance
- > Innovation
- > Approach
 - > Aim 1
 - > Aim 2
 - ➤ Aim 3

Option 2:

- > Aim 1
 - Significance, Innovation, Approach
- > Aim 2
 - Significance, Innovation, Approach
- ➤ Aim 3
 - Significance, Innovation, Approach

Additional Section Required for R15 Proposals (part of facilities section)

- A profile of available students of the applicant school/academic component and any information or estimate of the number who have obtained the baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences during the last five years.
- A description of the special characteristics of the university that make it appropriate for an AREA grant, where the goals of the AREA program are to: (1) provide support for meritorious research; (2) strengthen the research environment of schools that have not been major recipients of NIH support; and (3) expose available undergraduate and/or graduate students in such environments to research.

Additional Resources for Proposal Development

NIH Database of Sample funded Proposals

Funded R15 Proposals

Funded RO3 Proposals

Step-by-Step proposal preparation guidance from the NIH's Institute of Allergy and Infectious Diseases

NIH grant Writing Tip Sheets

Prepare proposal page of ORSP's Website

Preparing the Budget

What do you need to successfully complete the project?

- Summer Salary
 - how many months for how many years
 - Academic Year Course release (AWA)
- Collaborations within WCU
 - Co-Pi's/Senior Personnel (others needed for expertise)
 - Evaluation or Program assessment
- Undergraduate/Graduate Hourly Student Workers
 - how many hours, how many weeks, summer/AY, rate of pay
- Graduate Assistant
 - Full time is 12 credits; 20 hours a week

Amounts should be:

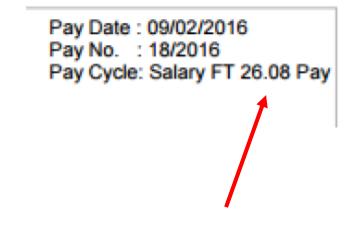
Realistic and reasonable

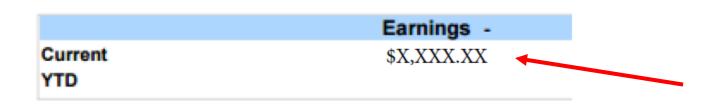
Well-justified and should establish need

Consistent with program guidelines

Withstand Public Scrutiny

How to Calculate your 9month Salary





To Calculate 9 month pay: Multiply 26.08 times \$X,XXX.XX enter the resulting Number in Cell G9 of the WCU Budget Builder.

Preparing the Budget (Con't)

- Travel (conferences or for research purposes)
 - When, where, how long, and how many travelers
- Specialty Supplies/Equipment
- Consultants/Contractors
 - Who, how many hours, rate of pay
- Subawards
 - What Institution, who will be the PI
- Advisory Board Honorariums
- Human Subject Incentive Payments

Enter all information into WCU Budget Builder or e-mail information to your Grants Specialist

WCU Budget Builder can be found at

http://wcupa.edu/research/prepareProposal.aspx

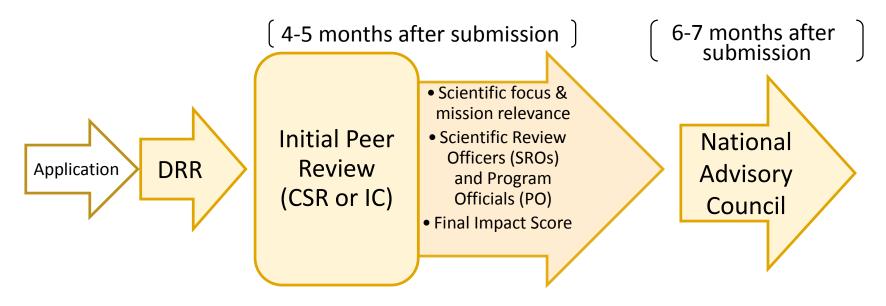
Prepare Budget

Work closely with your research office representative to dev

Build your budget by using WCU's customized <u>Budget Builder</u>

our budget

NIH Review Criteria and Policy



For each application:

≥ Three qualified reviewers are assigned for in-depth assessment

Study sections make recommendations on:

- Scientific and technical merit
- Impact
 - Impact scores
 - Criterion scores
 - Written critiques
- Other review considerations

Get inside information:

Visit the NIH Reviewer
Resources Website

Scored Review Criteria

- All Applications receive individual, numerical scores from assigned reviewers (usually 3).
- The following categories are scored:

Significance

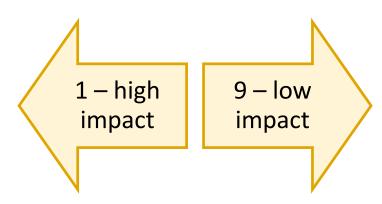
- Approach

See Review Criteria and Definitions

Investigator(s)

- Environment

- Innovation
- Reviewers give numerical scores for each category
 - 1 (exceptional) to 9 (poor)

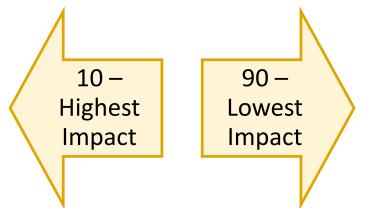


Score Descriptors

Score	Descriptor
1	Exceptional
2	Outstanding
3	Excellent
4	Very Good
5	Good
6	Satisfactory
7	Fair
8	Marginal
9	Poor
	1 2 3 4 5 6 7 8

Final Impact Scores (assigned at initial peer review for applications that are discussed)

- Voted on by all eligible SRG members, not just assigned reviewers
- Calculated by averaging all reviewers' votes and multiplying by
 10. Range from 10 through 90
- Impact scores are available in about 3 days after the initial peer review meeting
- Summary statement is viewable in eRA Commons within 30 days of initial peer review meeting.
- Contact your program officer after reading summary statement (hopefully he/she knows you by now)



Streamlining Applications (Not Discussed)

- All applications are peer-reviewed and scored before study section meets.
- Streamlining allows discussion of more meritorious applications.
- Requires full concurrence of the entire study section
- Summary statements contain:
 - Reviewer critiques
 - Criterion (individual reviewer) scores
- Applications designated as ND do not receive a final impact score

Final Step of Review: National Advisory Council

- Broad and diverse membership
 - Basic/research scientists
 - Clinician scientists
 - "Public" members
- Recommend applications for funding
- Awards cannot be made without Council approval
- The Advisory Board/Council also considers the IC's goals and needs and advises the IC director.
- The IC director makes final funding decisions based on staff and Advisory Council/Board advice.

Thank You



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