



## How to prepare for transition from a K grant to a R grant

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# Outline

- Strategies for making the most of the research you conduct during the K award
- The importance of relationship building at the NIH
- Keep an eye out for the FOAs and RFAs that are the best fit for your work
- Getting Organized:
  - Your results
  - Your team
  - Your timeline

# Making the most of the K research

- Early on, try to identify at least one research question and testable hypothesis that is important regardless of the direction or significance of your findings.
- If you can link the K research to the first R grant this will help you have strong preliminary studies and it will be easier to defend why the work proposed in the R is the most important and logical next step and why you are the best PI to do this work

# Making the most of the K research

- Get out front with your research findings so that you start to develop a name and identity in your field
  - Present your work at the most important meetings
  - Take advantage of opportunities to participate in NIH conferences and other symposia in your field
  - Get to know the most prominent scientists in your field so that you can get their input on your work
  - Publish... try not to get scooped!
  - **Time** is your most precious commodity, don't waste it on low yield activities – If you are not sure which ones fall in this category, talk to your mentor

# Be aware of who else is working in your area of research!

- Literature search
  - Pubmed: what has been published
  - Google scholar (may pick up abstracts presented at meetings)
- NIH reporter (grants that have been funded already)
  - <http://projectreporter.nih.gov/reporter.cfm>

# Making the most of the K research

- Look for opportunities to be independent of your mentor
  - In some fields this is accomplished by working and publishing with more than one senior researcher
  - Or, you may have the opportunity to “PI” a smaller foundation grant in your field that is related to or is an extension of your main work
  - Early on, talk to your mentor about what you should do now or in the next couple of years so that when the first R goes in with you as PI there will not be questions about your independence.

# Relationship Building at the NIH

- Establish relationships with the program officers at the institute(s) in your research area
- Know the institute's priority areas in your field
- Each Institute handles grants in slightly different ways
- 2 parts:
  - Program- Includes the Institutes that set the research priorities – get to know your institute's priorities!
  - Review - CSR or Center for Scientific Review
    - Evaluates the scientific merits of the proposals
    - <http://www.csr.nih.gov>

The best way to know your institute

Sign up for the *NIH GUIDE ListServe*

<http://grants1.nih.gov/grants/guide/listserv.htm>



once a week receive a Table of Contents with 'links' to PAs, Notices, FOAs and RFAs

# Resources

- NIH Guide for Grants and Contracts
- Institute web pages
- Grants Net (<http://www.grantsnet.org>)
- Mentors and colleagues
- NIH staff

# NIH Program staff

- ❖ Program Director/Administrator or 'Project Officer'
- ❖ Work for an Institute or Center
- ❖ Handle pre-application questions
- ❖ Manage grant portfolios
- ❖ Develop RFAs and PAs
- ❖ Observers at study section meetings
- ❖ Handle post-review issues
- ❖ Send out summary statements
- ❖ Initiate funding plans
- ❖ Review yearly progress reports

# Governmental Alphabet Soup

- NIH - National Institutes of Health
- AHRQ - Agency for Healthcare Research and Quality
- PCORI – Patient Centered Outcomes Research Institute
- RFA - Request for application
- RFP - Request for proposals
- PA - Program announcement
- FOA – Funding opportunity announcement

# Funding the transition from K to R

- Look for funding announcements, preferably RFAs or FOAs that have specific dollars allocated to your area
- What if there aren't any or what if the pay lines are unrealistically low?
  - Consider foundations, professional organizations, industry, or institutional grants to tide you over
  - Awards from these sources can keep you working, publishing, and staying active in the field and can strengthen your portfolio while you try to identify the best opportunity at NIH

# First steps in R proposal preparation

- Take a hard look at what you have published and try to build the R around your most significant research findings – *this may or may not be your K funded research*
- Decide where will it go and/or who your audience is
- Check NIH Reporter to make sure that the study isn't already underway
- Requires several months of reading, organizing, writing, and revising

# Review and Award Cycles

	Cycle I	Cycle II	Cycle III
<b>Scientific Merit Review</b>	June – July	October – November	February - March
<b>Advisory Council Round</b>	August or October *	January	May
<b>Earliest Start Date</b>	September or December *	April	July

\* Advisory Council Round for Cycle I applications may be August or October, and their earliest project start date may be September or December respectively.

# First steps in proposal preparation

- EARLY ON talk to the scientific administrator!
- Follow the written guidelines from the funder carefully
  - Outline of the structure
  - Page limits
  - Font sizes
  - Funding limits
  - Elements that must be included
  - Priority areas

# Get Organized

- Work from an outline
- Establish a timeline for completing the proposal - make time to work on this
- Have the project team meet periodically
- Give assignments with deadlines
- Make deadlines for yourself
- Find a model proposal
  - recently funded by the same agency
  - look over the reviews if you can get a hold of them
- REVIEW, PRETEST, REVISE REPEATEBLY

# Project Team

- Select and organize the project team
  - Will more than one person be writing?
  - Make sure to include co-mentors with the main areas of expertise needed to design and complete the study-- step back and think carefully about what areas are critical to cover

# Summary

- Things won't go as smoothly as this talk sounds
- Be flexible, take advantage of unexpected opportunities when they come your way
- Be very protective of your time
- The drought at NIH won't last forever, so be strategic, keep doing the research you love and you will be in the strongest position to compete when the time is right to submit an R

# NIH Award Success



# NIH Reviewer Guidelines

# Significance

- Does this study address an important problem?
  - *Do you make a compelling case?*
- If the aims of the application are achieved,
  - *How will scientific knowledge be advanced??*
- What will be the effect of these studies on the concepts or methods that drive this field?
  - *How might this change the field?*
  - **Be convincing!!!**

# Approach

- Are the *conceptual framework*, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Is there an appropriate work plan included?
- Does the project include plans to measure progress toward achieving the stated objectives?
  - How will you know when you are half way there?

# Innovation

- Does the project employ novel concepts, approaches or methods?
  - Can be novel to your area
- Are the aims original and innovative?
- Does the project challenge or advance existing paradigms or develop new methodologies or technologies?

# Investigator

- Is the investigator *appropriately trained* and well suited to carry out this work?
- Is the work proposed *appropriate to the experience level* of the principal investigator and other significant investigator participants?
- Is there a *prior history* of conducting (fill in area) research? *Does not fund empty aspirations!*
  - *Publications and prior grant funding are great evidence*

# Environment

- Does the scientific environment contribute to the probability of success?
- Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
- Is there evidence of institutional support?
- Is there an appropriate degree of commitment and cooperation of other interested parties *as evidence by letters detailing* the nature and extent of the involvement?

# Budget

- Are all requests justified scientifically
- Do special items have quotes
- Is the project *feasible with the given budget*
  - Low budget often viewed worse than high,
    - Low budget - *applicant does not understand* what is need to do the work - may worsen the score
  - High budget: will get cut but usually not worsen score, unless ridiculously high

# Other Key areas

- Protection of human subjects (*closely reviewed*)
  - HIPAA plan
  - data and safety monitoring plan
  - Inclusion of women, minorities & children
  - Recruitment plan
  - *Evidence (not plan)* of proposed partnerships
- Animal welfare
- Biohazards
- **Evaluation**

# Specific Aims

- Each aim should be described in 1 or 2 sentences in the active voice
- The aims need to be in a logical sequence
  - Order of importance
  - Chronological order
  - Descriptive Aims followed by Analytic Aims
- The aims establish a parallel structure that can become the organizing force for the whole proposal
- Should be easy to read, interesting, and take up 1 page or less

# Methods

- Overview of design +/- conceptual model
  - Study subjects - selection criteria, sampling frame, recruitment plans
  - Measurements - Use Tables!
    - Predictors, outcomes, confounders
  - Pretest plans
  - Analysis plan
    - Organized by hypothesis
    - Justify the modeling strategy selected
    - Include a discussion of power

# Abstract

- Concise summary of the whole project
  - Usually written last
  - REVISE THIS MANY TIMES!
  - It may be the only part many reviewers read

# NIH Award Success



# NIH Updates



# Rigor and Transparency: new requirements

- 4 new areas of focus
- New instructions for Research Strategy
- New attachment: “Authentication of Key Biological and/or Chemical Resources”
- New review criteria

See NOT-OD-16-011

# Rigor and Transparency: New Scored Review Criteria

- **Significance:** “Is there a strong scientific premise for the project?”
- **Approach:** “Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”
- **Approach:** “Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?”

# 4 New Focus Areas

1. **Scientific Premise** for the proposed research
2. **Rigorous Experimental Design** for robust and unbiased results
3. Consideration of **Relevant Biological Variables**  
(will hold for clinical/admin variables)
4. **Authentication** of key biological and/or chemical resources (all data resources)

This applies to the full spectrum of research, from  
basic to clinical

# New Instructions for Research Strategy

- **Significance:** “Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to support your application.
- **Approach:** “Describe the experimental design and methods proposed and how they will achieve robust and *unbiased* results.”
- **Approach:** “Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans....”

# What is Scientific Premise?

- **Scientific Premise** = Research that is used to form the basis for the proposed research questions
- Describe general strengths and weaknesses of prior research that are crucial to support the application
- Include attention to rigor of previous experimental designs...

# Significance

- Importance of problem
- Describe barriers to progress in the field
- How the project will improve knowledge
- How the field will change after project

# Significance Section

- Within Significance subsection of Research Plan include subheading: **“Scientific Premise”**
- 1-2 paragraphs describing foundation of application
- Discuss current state of knowledge in the area
- Include brief description of your preliminary data (strengths)
- Describe knowledge gap that your proposal will address

# What is Scientific Rigor?

- Strict application of scientific method to ensure robust and unbiased experimental design, methodology, analysis, etc...”
- Includes full transparency in reporting experimental details...”

# Sample Elements of Rigorous Experimental Design

- Appropriate controls
- Replication of experiments
- Randomization
- Blinding
- Sample size/study power
- Statistical methods
- Missing data (plan to address)
- Others as appropriate

# Approach subsection of Research Plan

- Within Approach subsection of Research Plan include subheading(s): “**Rigorous Experimental Design**”
- Highlight key elements of rigor (which may be woven through your aims)
- This makes it easy for reviewers to find and evaluate

# Approach subsection of Research Plan

- Include subheading “Consideration of Relevant Biological Variables”
- Demographics, clinical conditions, health behaviors, community level factors, etc.
  - How to address? Which areas have measured vs. self reported vs. surrogate values, etc. Are the measured baseline or repeated.
  - Justify why limited to certain subgroups
  - How will the data be treated?
- Again, make it easy for reviewers...

# What is Authentication of Key Variables?

- Originally targeted for key Biological and/or chemical resources.
- Cell lines, specialty chemicals, antibodies, other biologics
- Same would hold for variables in data sets.
  - E.g. how is BP determined, how was the primary data set merged with what data sets, how is the merge validated, etc.

# New Attachment: Authentication

- “Authentication of Key Biological and/or Chemical Resources”
- Describe methods to ensure the identity and validity of key biological and/or chemical resources (may include cell lines, specialty chemicals, antibodies, other biologics).
  - Do not put preliminary data and other methods in this section
- Not structured for Health Services Research but strengthen your application by adding

# Authentication Attachment Guidance

- **Key Biological Resources** that will be utilized in this proposal include:
  - Cell lines: xxxxx
  - Transgenic mouse strains: xxxxxx
  - Antibodies: xxxxx
  - **Cell lines** will be validated via...
  - **Transgenic mouse strains** are validated by...
  - Blood Pressure will be validated by.....
  - Diagnosis of diabetes mellitus will be determined by  
.....

# New Biosketch Format (May 25, 2015)

- 5 page limit (increased from 4)
- Scientific accomplishments (describe up to 5)
- Link to publications
- A URL for a publication list is optional but must be to a government website (.gov) like My Bibliography
- Allowing publications and research products to be cited in both the personal statement and the contributions to science sections
- Graphics, figures and tables are **not allowed**

NOT-OD-16-004

# Other Grant Changes (Jan 25, 2016; NOT-OD-16-004)

- **Definition of Child** = <18 years old (previously <21)
- **RESEARCH TRAINING**
- "Recruitment & Retention Plan to Enhance Diversity"
  - applicants will be asked to focus on recruitment
- "Human Subjects/Vertebrate Animals"
  - applicants must describe how the institution will ensure that trainees only participate in exempt or IRB/IACUC approved human subjects research
    - No longer necessary to provide a list of potential grants trainees may work on and associated IRB info
- "Progress Report"
  - Requirement to report on publications that arose from work conducted by the trainee while supported by the training grant will be moved to the Just-in-Time process