R Awards How to write, and the review process

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(help from Joel Bennett)

- 1. Choosing the appropriate R-award mechanism
- 2. Rules for Preparing a Successful Grant Application
- 3. What to Emphasize When Writing Your R01
- 4. Common Problems Cited by Peer Reviewers

The Three R's

R01 R21 R03

R01: NIH Research Project Grant Program

- The original NIH grant mechanism
- Usually investigator-initiated in response to the RO1 Parent Announcement or a Program Announcement highlighting particular scientific areas.
- 5 years, max \$250,000/yr (if modular).
- Renewable. Supplements and amendments are allowed.
- 1+12pp
 - 1p Specific Aims
 - 12p Research Strategy (Significance, Innovation, Approach)

R21: Exploratory/Developmental Research Grant Program

- "supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical...research"
- High risk/high gain
- Preliminary data are not required
- 2 years, \$275,000 total
 Typically \$150,000 yr 1, 125,000 yr 2 or vice versa
- Non-renewable
- 1 + 6 pp
 - 1p Specific Aims
 - 6p Research Strategy

When to choose an R21

- Exploratory, novel studies that break new ground or extend previous discoveries in new directions.
- High risk-high reward studies that may lead to a breakthrough in a particular area, or result in novel techniques, agents, methodologies, models or applications that will impact biomedical research.
- Projects should be distinct from those supported through the traditional RO1 mechanism.

Myths about the R21

- It's a good way to get your lab started.
 - These are short term grants, with no prospect for renewal. You'll need to start writing another grant right away, but will be poorly positioned if you put your best ideas in your R21.
- They're easier to get than RO1's because they don't require preliminary data.
 - R21's are scored together with R01's but funded separately. They are typically very competitive.
 - No matter what they tell you, most competitive R21's have quite a bit of preliminary data.

• It's a mini-R01.

 "Projects of limited cost or scope that use widely accepted approaches and methods are better suited for the RO3 small grant mechanism"

RO3: Small Research Grant Program

- "Discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding."
- Mini-R01
- 2 years, max of \$50,000/year
- Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.
- Non-renewable
- 1 + 6 pp
 - 1p Specific Aims
 - 6p Research Strategy

When to choose an RO3

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

Not all institutes accept investigator-initiated R21's

- Institutes that accept Investigator-Initiated RO3 Applications in response to the Parent R21 Announcement NCCAM, NEI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIDDK, NIEHS, NIMH, NINDS, NINR, NLM.
- Institutes that ONLY accept R21 applications in response to their specific funding opportunity announcements:
- FIC, NCI, NIMHD, NCRR, NHLBI, and NIGMS.

Not all institutes accept investigator-initiated R03's

- Institutes that accept Investigator-Initiated RO3
 Applications in response to the Parent RO3
 Announcement NHGRI, NIA, NIAAA, NIAID, NIBIB, NICHD, NIDA, NIEHS, NIMH, NINDS, NINR
- Institutes that ONLY accept RO3 applications in response to their specific funding opportunity announcements: <u>FIC, NCCAM, NCI, NCRR, NEI, NHLBI, NIAMS,</u> <u>NIDCD, NIDCR, NIDDK, NIGMS and NLM</u>
- Institutes that DO NOT use the RO3 mechanism: <u>NIMHD</u>

2. Rules for Preparing a Successful Grant Application

> Obtaining an RO1 is a <u>Highly Competitive</u> Process

>It is also an <u>Anonymous Process</u> in the sense that the RO1 is Scored on basis of what is Written in the Application

>Preparing a Competitive RO1 application is an <u>Acquired Skill</u>, ie., the more you have to do it, the better you get at it.

>Obtaining and renewing an RO1 is an important <u>measure of success</u> in academic medicine

Obtaining Grant Support from a Subspecialty Organization is a Good Way to Start a Career

> Many Associations have grant programs geared to the beginning investigator

> They may be less competitive, at least in the sense that applicants are at the same stage of their careers

> They provide a way to generate the preliminary data that will be needed for an R01

> They provide a way to establish an record of independent publication

> They demonstrate that you have been successful in obtaining grant support in a peer-reviewed setting

> They provide GOOD PRACTICE

Review Process

- Study section has about 20-30 people
- 3 people actually read the grant
- Initial scores are given by the 3 reviewers
- Primary reviewer describes grant
- Secondary and tertiary add anything else that hasn't been mentioned.
- Open to discussion. Other committee members are looking at the grant online and may weigh in. Around 15 min allotted to each grant.
- RO1s can be triaged and not discussed at all

Approach the Preparation of Your RO1 Application as a Teaching Exercise

>Lead the Reviewer through your proposal

>Organize the Proposal in Logical Order

>Use an Outline or Introductory Paragraph at the Beginning of Each Aim or Subaim to tell the Reviewer what to Expect later on.

Make It Easy for the Reviewers to Read Your Proposal

Grant Reviewing is Subjective, Don't Start Off on the Wrong Foot!

Figures are good,

But,

- 1. Keep them simple
- 2. Make sure there is a figure legend and they are referred to in the text

Have someone you trust to tell you the truth read your proposal before you submit it.

3. What to Emphasize When Writing Your R01

Address the NIH Review Criteria:

Significance Investigators Innovation Approach Environment

Significance (Who cares?)

In an era when funding is severely restricted, projects that are the most clinically and/or biologically significant are likely to be viewed most favorably. It is IMPORTANT to emphasize the significance of your project.

<u>Investigators</u>

Pay careful attention to your biosketch. Most reviewers will not know who you are and make use of your biosketch to assess your credentials and accomplishments

Innovation (outdated?)

Although reviewers are attracted to novel ideas and methods, be careful. Propose good solid experimentation about a significant topic. The goal is to get "the money".

Approach (what is the experimental plan?)

> How much preliminary data is required? Although less is expected from new investigators, it is important to establish feasibility and some evidence of experimental competence

> Provide clear rationales for proposed experiments

> Don't be overly ambitious, propose what you think you can reasonably accomplish over the tenure of the grant (provide a tentative timeline for proposed experiments)

> It is essential to provide potential alternative approaches, not every experiment works! Use of more senior investigators as consultants is reassuring.

> Provide essential experimental detail, but don't write a lab manual

> Don't neglect statistics

Don't Neglect the Abstract

Although it is likely that only 2-3 members of a study section will read your proposal in detail, every member votes. What the other members know independently about your proposal may be limited to the abstract.

<u>Budget</u>

The charge of a study section is to evaluate and rank the science of the proposals they review. But they also review the budget after the science has be scored.

>Be careful to justify each item in your budget.

>Propose a budget that you think is realistic for work you propose and say so. Submit to Your Proposal to the Appropriate Study Section and Institute

CSR Study Sections and Study Section members are listed on the OER website

 \succ Pick a Study Section that is likely to be familiar with the work you propose.

> Consider requesting that your proposal be crosslisted in multiple Institutes (e.g. NCI and GM).

>Ask a more senior colleague for advice about where to direct your proposal

> State your preferences in the cover letter with a sentence justifying your choice

4. Most Common Problems Cited by Peer <u>Reviewers</u>

- * Problem not important enough
 - Study not likely to produce useful information
 - Studies based on shaky hypothesis or data
- * Alternative hypotheses not considered
 - Methods unsuited to objective
 - Problem more complex than applicant realizes
- * Too little detail in Research Plan to convince the reviewers that the applicants knows what he/she is doing

* Overambitious research plan

Investigator too inexperienced with proposed techniques

- * Lack of focus in hypotheses, Aims, or Research Plan Research priorities not clearly defined
- * Project is a fishing expedition
- Proposal is technology driven (method in search of a problem)
 No rationale for the proposed experiments is provided
- * Relevant controls are not provided

* Insufficient preliminary data or preliminary data do not support the projects feasibility

****** Insufficient attention to statistics

What if You Do Not Get the Money?

• <u>Try again</u>

- Get advice from the Program Officer
- Carefully read the pink sheets
- Discuss the grant and reviews with senior colleagues with expertise in the subject area of your grant
- Before resubmitting the grant, make sure you can address the major critiques
 - The next reviewers will see the pink sheets from the previous submission
 - The most important things to address will be in the summary paragraph written by the SRA
 - If you cannot do what they want, have a good reason why you need not
 - In the resubmission, answer all of the major concerns (both in your three page introduction and the body of the grant)