Grant-writing from a reviewer's perspective

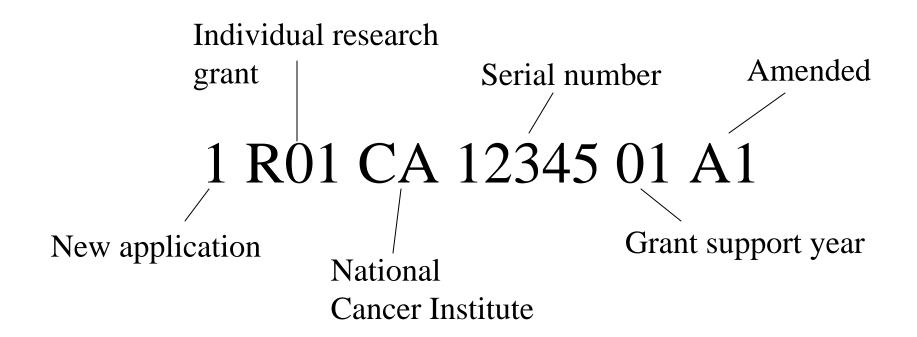
With credit to Ogden and Goldberg,

Research Proposals: A Guide to

Success

What happens to your grant at NIH

- 10,000 grants arrive per grant cycle
- Grants are date stamped an logged into NIH database
- ~12 Referral Officers review contents and assign Integrated Review Group (IRG), constituent Study Section, and Institute
- Referral Officers assign unique number
- A computer-generated letter is sent to the applicant
- Scientific Review Administrator of the Study Section assigns reviewers



Before the Meeting

- A CD arrives 6-8 weeks before the meeting
- A folder includes paper copies of the grants assigned to the reviewer
- Reviewers submit any conflicts of interest
- Reviewers read grants on airplane rides, during football games....

The Study Section

Assignments

- primary & secondary: written reviews
- tertiary ("reader"): read & comment

Review Criteria

defined for each application type

Priority Scores

– scale: 100 (best) to 500 (worst)

• "The assignment process is a collegial one, with interaction, when necessary, on a case-by-case basis among Referral Officers, study section Scientific Advisory Officers, Institute program representatives and applicants"

Before the Meeting

- Reviewers fly to BWI/ Reagan National
- Take cab to lovely Washington suburban hotel
- Report to a conference room with computer, computer disk for a delicious continental breakfast



How I feel about being on study section

- I ought to do it (good citizenship)
- It connotes national recognition
- I learn about grantsmanship
- It takes time away from the things I should really be doing
- It forces me to read science that I might not otherwise read
- I don't like traveling and being away from my family

The Meeting

- Committee members introduce themselves
- SRA goes over the rules
- SRA reads the names of the grants that have been triaged if anyone objects to triaging a given grant, that grant must be reviewed.

The Study Section

- 15 to 18 regular members and often as many as 5 or 6 ad hoc members
 - Members have their own R01s
- Most sections meet 3 to 4 times a year.
- Study sections view from 50 to 120 proposals
- Reviewers are paid ~\$200 per day

The Meeting

- SRA introduces the grant
- Those with conflict leave the room
- Primary, secondary and tertiary reviewers verbalize their priority scores
- Reviewers provide their comments
- Reviewers recapitulate their scores
- Study section members mark vote (may be asked to announce if they are outside the range)

For the Clinical Cardiovascular Study Section the third reviewer is always a biostatistician.

Scoring

- Priority score 1 to 5
- Among those not triaged 1-3
- Converted to percentile
 - For regular study sections: based on current plus two past review rounds
 - For Special Emphasis Panel: if 30% regular members, current plus 2; otherwise against all Center for Scientific Review (CSR) study sections

Review Criteria - Science

- Significance
- Approach
- The investigator
- Innovation

Review criteria career development awards

Candidate

Career development plan

Research plan

Mentor

Environment & Institutional Commitment to the Candidate

Training in Responsible Conduct of Research Letters of Reference and Mentor(s) statements Plans to Evaluate Progress

What determines the score

- The quality of the grant
- The reviewers

What determines the reviewer:

- The Study Section
- Luck

Know your study section

1. Don't p- off the reviewer.

2. Wow the reviewer with your thoughtfulness

Characteristics of a good grant

- The problem is important.
- The investigation is directed at fundamental mechanisms that are basic to normal function or a disease process.
- Specific hypotheses about those mechanisms are presented and feasible tests of the hypotheses are suggested.
- Data sought are quantitative and subject to statistical validation.
- The PI has a proven record of success with the techniques proposed, is well equipped, and is a member of an established group with which collaboration is productive.

Characteristics of a good grant

- Exposition is clear, logical and brief
- There are no typos
- The science is as close as possible to the state-of-the-art
- Daring methods are supported by solid preliminary data

The problem is important.

Example from a triaged grant:

Lower limb ischemia is a serious cause of morbidity and mortality. Revascularization reduces the number of amputations and the deaths. Nevertheless the factors that predict quality of life in patients with lower limb ischemia are not known....

Specific hypotheses about those mechanisms are presented and feasible tests of the hypotheses are suggested.

Consider

To determine the effect of ACE inhibition on vascular t-PA release.

Versus

To test the hypothesis that ACE inhibitors increase endothelial t-PA release through endogenous bradykinin.

- "With some thought it is almost always possible to transform a study based on trivial or phenomenological hypotheses into one involving basic mechanisms and scientific important hypotheses."
 - Ogden and Goldberg, Research Proposals: A
 Guide to Success

Data sought are quantitative and subject to statistical validation.

- It's not good to hear:
 - This methodology has not been validated
 - Brachial artery dilation is notoriously operatordependent, but the PI does not give....
 - There is no analysis plan
 - In the Preliminary Studies section the author does not give the N or say whether he has shown SEM or SD...
 - There is no explanation of how the power calculations were derived
 - There is no biostatistician, data entry personnel...

10 most common reasons for proposal failure

- 1. Lack of original ideas.
- 2. Diffuse, unfocused, or *superficial* Research Plan.
- 3. Lack of knowledge of published relevant work.
- 4. Lack of experience in essential methodology.
- 5. Uncertainty concerning future directions.
- 6. Questionable reasoning in experimental approach.
- 7. Absence of acceptable scientific rationale.
- 8. Unrealistically large amount of work.
- 9. Lack of sufficient experimental detail.
- 10. Uncritical approach.

Appearance – don'ts

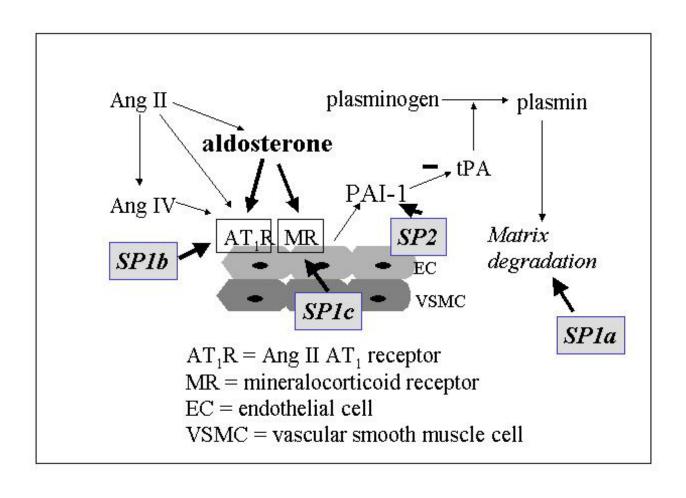
Things that p. off a tired reviewer

- 2 pounds of appendix in addition to 25 pages of text
- "cheating" with the use of small type font with crowded pages
- No double spaces, no indentations, no figures, no titles

Appearance – do's

- Double space between paragraphs
- Use 1.2 line spaces between lines
- Use paragraph titles to facilitate skimming
- Use diagrams
- Make sure figure legends are readable
- Format all of the biosketches the same way
- Search to make sure that abbreviations are consistent (e.g. t-PA or tPA throughout)

Example of an hypothesis figure



• "A strong proposal will give the appearance of being well organized and readable at first glance."

Achieving this takes time.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

Grant Application

PHS 398 (Revised 9/2004, Interim Revision 4/2006)

See the 4/7/2006 NIH Guide Notice NOT-OD-06-056 for important changes to this version.

All notable changes made to PHS 398 form pages are listed at the bottom of this page (Updated 11/15/2006).

DOWNLOADABLE INSTRUCTIONS AND FORM FILES

Some of the MS Word and PDF files are large and may take a few minutes to download.

PHS 308 Instructions - 4/2006 Revision

The pink sheets

• They are not pink.

Among ultimately successful proposals
48% of new proposals require amending
38% of competing renewals require amending

• Take a day or two to feel misunderstood and then think carefully about the comments.



Home

Links Help

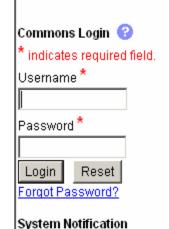


INTERNET ASSISTED REVIEW ALERT 10/27/2006: Due to the high volume of Review Meetings in the coming week, we will be providing IAR with Internet support between the hours of 10 a.m. and 3 p.m. this weekend 10/28 and 10/29. We encourage you to take advantage of our new w support at http://ithelpdesk.nih.gov/eRA/. When requesting support please supply as much of the requested data as possible for faster service.

Version 2.7.4.5

Electronic Submission Tip: Learn about the most frequent application errors at Avoiding Common Errors.

Elimination of Paper Summary Statements: NIH is eliminating the mailing of paper summary statements. Click here for the NIH Guide Notic



Primary Features of Commons include:

- Status Allows Principal Investigators to review the current status of all their grant applications and review detailed information associated with their grants. Institution Officials (i.e., Signing Official (SO) or Administrative Official (AO) associated with the institution) can see a summary view of grant applications, review the Notice of Grant Award, and access the Progress Report face page.
- eSNAP Allows an institution to review non-competing grant data and submit a progress report online.
- X-Train Not currently available.
- Internet Assisted Review (IAR) Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SRAs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRA or GTA.
- Financial Status Reports (FSR) Allows electronic submission of financial information associated with a grant.
- Administration Provides the ability for an institution to create and manage user accounts associated with its institution. Additionally, it allows the institution's Signing Official (SO) to maintain the institution information on file at the NIH.
- **Demo Facility** Demo Facility allows you to try most of the capabilities of the NIH eRA Commons in a sample environment.

About the Commons

- Scope and Purpose
- ▶ Frequently Asked Questions
- Grantee Organization Regis
- ▶ eRA Contacts
- ▶ Enter eRA NIH Commons [

Links

- Commons Support Page
- ▶ CRISP
- eRA Home Page
- ▶ Electronic Application Recei
- Grants.gov
- ▶ <u>iEdison</u>
- Loan Repayment Program
- National Institutes of Health
- ▶ Public Access Policy Page

The purpose of a response

- Establish that the resubmitted proposal is, indeed, revised
- Identify major changes
- Acknowledge and correct deficits in the original proposal
- Correct errors of the IRG

Reading between the lines

- If there is a disparity between pink sheet comments and score, make every effort to find out why (e.g. talk with the SRA)
- Try to figure out who your reviewers are
- Consider asking a former (before your review) member of a study section

Responses should

- Acknowledge that the initial proposal is flawed
- That the review was excellent and helpful
- That the suggestions improved the revision

• The tone should be perceived as conciliatory, but not sycophantic.

INTRODUCTION

We are grateful to the reviewers for their evaluation of our proposal. We are pleased that the reviewers found that the proposed work explores "a novel hypothesis" and has many strengths, "the PI, strong preliminary data, and the excellent environment" and that the amended protocol was "much-improved." We have further modified the proposal based on their comments. Changes to the proposal are marked.

The reviewers expressed concern that the mouse studies proposed in SPECIFIC AIM 1 were not within the PI's expertise and advised that the inclusion of additional experts would significantly strengthen the proposal. We regret that we did not adequately convey the PI's role in obtaining the "strong preliminary data" presented in the grant, the continued input of the PI's long-time collaborator Dr. Doug Vaughan in the proposal, the expertise of the PI's Co-Investigators, or the expertise available to the PI through the Vanderbilt Mouse Metabolic Physiology Center. We have responded to the reviewers' concern by enlisting Dr. Tadashi Inagami, an investigator who has played a seminal role in the development and use of knockout mouse models for the study of the renin-angiotensin-aldosterone system (RAAS), as a Co-Investigator. We have also added Dr. Li-Jun Ma, a Research Instructor who trained with Dr. Agnes Fogo, to assist in the mouse infusion studies and tissue preparation. We further delineate here the expertise and resources included in the proposal that are relevant to SPECIFIC AIM 1.

Don't be lazy

• Don't be afraid to make major changes, E.g.

- Changes in personnel
- Dropping a specific Aim

On the falling sky

• "Paylines are shrinking..."

e.g. NHLBI 14%

New investigator RO1s 19%

with administrative 25% revisions

On the falling sky

- 12.2% of new submissions from Vanderbilt funded
- 42.5% of revised submissions from Vanderbilt funded