Grant Writing Essentials

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LONG-TERM STRATEGIES FOR SUCCESSFUL GRANT WRITING

1. Take the long view (look ahead)
2. Find someone who will share copies of successful grants
3. Investigate appropriate sources of funding (governmental agencies, foundations, Hopkins)
4. Stay informed about the grants scene (through grant administrators, colleagues, Internet)
5. Find an appropriate study section
6. Ask for feedback
7. Keep a grants notebook
8. Don’t be afraid to ask for help
9. Start early!!! Expect delays!

EXPECTATIONS OF GRANTING AGENCIES AND REVIEWERS

What the Granting Agency Will Ask About Your Grant:

$ Does it match the agency’s mission and priorities?
$ Is it interesting/innovative?
$ Is the design well conceived and described?
$ Is it based on previous work? Is it feasible?
$ Are the applicants qualified to carry out the research?
$ Is the institution supportive?

Questions You Need to Answer in Your Grant:

$ What problem have you identified? How does it match the funding agency’s interests?
$ What is the current status of the field, and what gap(s) are you proposing to fill?
$ What will you do to fill those gaps?
$ What have you already done to demonstrate the feasibility of your approach?
$ Where will the work be done, and by whom?
USEFUL WEB PAGES

At Johns Hopkins

www.welch.jhu.edu       Welch Library homepage
www.welch.jhu.edu/publish/grant.html       Useful grant resources
jhuresearch.jhu.edu/       JHU Research Projects Administration
www.hopkinsmedicine.org/research/ora       Johns Hopkins Medicine Office of Research Administration
www.jhsph.edu/ora/       SPH Research Administration
www.son.jhmi.edu/research/cnr/       SON Center for Nursing Research

At the NIH

grants.nih.gov/grants/oer.htm       Office of Extramural Research homepage
grants.nih.gov/grants/guide/index.html       Funding opportunities--general
cms.csr.nih.gov/ResourcesforApplicants/Policy/ProcedureReview+Guidelines/OverviewofPeerReviewProcess.htm       The peer review process (includes mock study section video)
csr.nih.gov/Roster_proto/sectionI.asp       CSR Study Section Descriptions
csr.nih.gov/Committees/rosterindex.asp       CSR Study Section Roster Index
era.nih.gov/ElectronicReceipt/applying.htm       Electronic submission of applications
niaid.nih.gov/ncn/grants/default.htm       NIAID “All About Grants” page
niaid.nih.gov/ncn/grants/app/default.htm       NIAID sample R01 grant
PARTS OF THE RESEARCH PLAN
for NIH R01 Grants
(Page limit: 25 pages for sections a - d)

a. SPECIFIC AIMS: What do you intend to do?
   (1 page recommended)

1. State your broad, long-term objective(s) (1-2)
   - to develop safe and effective vaccines against schistosomiasis
   - to elucidate the molecular mechanisms by which retroviruses exert an immunosuppressive effect on their hosts
   - to design effective home-based intervention programs for elderly Korean Americans

2. Briefly identify health-relatedness, rationale for proposed study, overall approach, hypothesis(es) to be tested (2-3 sentences)

3. State each specific aim (“to do” list; what you will do to test hypothesis)
   - optimal number is 3-5 aims
   - must be measurable
   - use active verbs (“to compare,” “to measure,” “to recruit”)

   SPECIFIC AIM 1. To design and synthesize 1-N-oxide iminosugar inhibitors of glycosidases
   SPECIFIC AIM 2. To evaluate in vitro the inhibitory potential of the glycosidase inhibitor candidates
   SPECIFIC AIM 3. To examine the effect of selected inhibitors on metastasis in a mouse model of lung carcinoma

4. For each specific aim, briefly outline the approach to be used to achieve that aim

5. Conclude with a statement of potential usefulness/importance of findings (optional)
b. BACKGROUND AND SIGNIFICANCE: Why is the work important? (2-3 pages recommended)

Background:
1. Critically evaluate existing knowledge

2. Identify gaps in knowledge
   - be objective
   - state the questions that remain to be answered

3. Show how your proposed studies will fill the gaps
   - relate your proposed experiments to specific aims
   - establish theoretical framework for your proposed studies

Significance:
1. Summarize potential importance, implications of your study
   (How will your research increase our ability to diagnose/manage/prevent disease? Increase our understanding of a disease or disease-related biologic process?)

2. Avoid citing well-known statistics on incidence, economic impact of common disorders

3. Consider a separate heading for this sub-section

c. PRELIMINARY STUDIES/PROGRESS REPORT: What have you already done? (6-8 pages recommended)

1. Show pertinent preliminary findings (can be unpublished)
   - provide data to support hypothesis
   - establish experience and competence of PI
   - show studies are feasible
   - relate findings to specific aims

2. Use tables and figures to showcase data

3. If new applicant, discuss relevant training
   - include work from other fields that indicates experience with proposed techniques
   - differentiate yourself from your mentor

4. List your relevant publications (required for progress report)
   - papers submitted or accepted for publication (not abstracts, talks)
   - optimum: ≥1 paper with PI as first author
   - for progress report, not counted toward page limit
d. RESEARCH DESIGN AND METHODS: How will you do the work? 
(remainder of 25 pages allowed)

1. Discuss overall design and specific methods to accomplish aims

2. Consider introductory paragraph to summarize research goal, gaps to be filled, underlying hypotheses, overall approach

3. Use specific aims as outline for section
   - restate each specific aim (same wording as Specific Aims)
   - summarize approach to carry out aim
   - provide rationale for approach

4. For each aim, describe specific experiments/interventions/protocols
   - include setting, subjects, variables, interventions, measures, analytic methods
   - be explicit in describing controls, inclusion/exclusion criteria, safeguards
   - be sure statistical analysis is impeccable (use statistician; justify tests used)
   - identify possible pitfalls and give alternative approaches

5. Describe specific methods to be used
   - can be subsection at end of each aim or General Methods section at end
   - reference familiar methods
   - reference and briefly describe if not common method
   - avoid “cookbook” style (show hands-on knowledge of technique)
   - use collaborators when needed (indicate who will do what)

6. Provide a tentative timetable/timeline for research

   One Possible Outline for RESEARCH DESIGN AND METHODS:

   Introductory paragraph–goal, overall approach, rationale

   Specific Aim 1. To..... (repeat aim word-for-word from Specific Aims page)

   Rationale – 1 paragraph (restate hypothesis specific to this aim, if appropriate)

   1. (Experiment 1)
   2. (Experiment 2)
   3. (Experiment 3)

   Potential Pitfalls/Alternative Approaches

   Specific Aim 2. To.....

   General Methods
e. HUMAN SUBJECTS

$ Must have IRB approval

$ Provide all written assurances required (e.g., inclusion of minorities, women, children; sources of research material; recruitment plans; risks; safeguards)

f. VERTEBRATE ANIMALS

$ Must have IACUC approval

$ Provide all written assurances required (e.g., justification of need; procedures for minimizing discomfort, euthanasia)

g. LITERATURE CITED

$ Be selective!

$ Aim for 30-50 references

$ Include title, all authors (within reason)

$ Use a consistent format; proofread diligently!

h. CONSORTIUM/CONTRACTUAL ARRANGEMENTS

i. RESOURCE SHARING

j. CONSULTANTS
OTHER ESSENTIAL ELEMENTS OF THE GRANT

TITLE

$ Do not exceed 81 characters, including spaces between words and punctuation

$ Be specific (this title must be used only for this grant and any continuation grants)

DESCRIPTION (Project Summary and Relevance)

$ Make sure it can stand alone

$ Include all parts of research plan (must reflect entire contents)

$ State the long-term objective(s)

$ Provide summary of background and overall approach

$ State specific aims (again, use exact same wording)

$ Succinctly describe research design and methods

$ Show the relevance (health-relatedness) of project

$ Do not use first person (only applies to this section)

APPENDIX

$ Can include 5 copies of relevant supporting material:
  -up to 10 relevant manuscripts (accepted or published), abstracts, patents
  -clinical protocols, surveys, questionnaires
  -glossy photos or over-sized illustrations (must also include photocopy within text)

$ Don’t use to avoid page limits!

BUDGET (grants now modular: request up to $250,000/yr. in modules of $25,000)

COVER LETTER (use to request Institute and study section; can ask to exclude a reviewer)
EFFECTIVE WRITING AND LAYOUT DESIGN

1. Think about your audience
2. Show your thinking
3. Use a picture
4. Keep information and structure parallel and consistent
5. Put important ideas up front
6. Make your writing simple and direct
7. Don’t trust your spell-checker too much
8. Follow formatting instructions carefully; do not right justify text
9. Use paragraphs to signal new ideas
10. Establish a logical hierarchy of headings; use it consistently

SUBMISSION AND REVIEW

NIH review is two-tiered:

1. Scientific merit (study section)
2. “Fit” with funding agency priorities (Advisory Council)
WHAT HAPPENS TO YOUR GRANT?
The NIH R01 Review Process

(Feb 5) Grant arrives at Center for Scientific Review

Assignment of appl. no., Institute, study section

10 days-  Notification of application number, Institute, study section assignment
6 weeks after submission 1°, 2° reviewers assigned,

Grants sent to study section

1 week before study section meets Reviewers identify grants to be “streamlined” (lower 50%)

Streamlined grant reviews returned (no score)

(June - July) Scientific merit review (Study section meets: upper 50% of grants discussed; priority scores assigned)

"Pink sheet” summary statement available to applicant with priority score and %ile

(Sept - Oct) Advisory Council review (funding)

Applicant notified of funding status

(December or later) Start date for funding
NIH Review Process—Important Steps:

1. **Notification of Institute and study section assignment, application number**
   - available online (eRA Commons) very soon after submission
   - if study section is not appropriate, request a change (in writing) NOW

2. **Submission of supplementary material by PI (before study section meets)**
   - can let study section know about additional publications or preliminary results (must contribute significantly to application)
   - contact Scientific Review Administrator (SRA) for permission and timeframe
   - do not try to submit <6 weeks before study section meets

3. **Discussion of grant by study section**
   - entire group votes to decide which grants will be “streamlined” (“triaged”)
   - roughly, lower 50% of grants in terms of scientific merit
   - are not discussed by study section
   - investigator receives 1° and 2° reviewers’ comments only
   - each remaining grant is discussed individually
   - 1° and 2° reviewers present written critiques
   - entire group discusses grant
   - each member assigns a priority score (1 [best] to 5)
   - SRA produces summary sheet (“pink sheet”): edited version of written critiques and summary of additional discussion, with final averaged priority score and %ile

4. **Consideration by Advisory Council**
   - recommendations of study section are discussed
   - assignment of funding is made
NIH Grant Review Criteria:

1. Significance
- Does this study address an important problem?
- If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
- What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach
- Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation
- Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators
- Are the investigators 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 researchers?
- Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. Environment
- Does the scientific environment in which the work will be done contribute to the probability of success?
- Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements?
- Is there evidence of institutional support?

Applications are also reviewed for:
- adequacy of plans to include both genders, minorities, and their subgroups as appropriate
- adequacy of plans for recruitment and retention
- reasonableness of proposed budget and duration
- adequacy of proposed protection for humans, animals, or the environment
Decisions from the Study Section:

1. Streamlining (“triage”)
2. Summary statement (“pink sheet”)
3. Priority score (e.g., 231), percentile

Responding to the Summary Statement:

1. Read, react and recover

2. Reread the reviews
   - outline each point made by reviewers
   - show review to an experienced grant writer for input

3. Reread your grant

4. Ask for feedback, advice

5. Decide how to respond; develop a timeline for resubmission
   - can only resubmit ≤ 2 times, within 2 years of original date of submission
   - deadlines are March 5, July 5, November 5

6. Take heart! Success rate for first revisions is ~50%