R01 NIH Grants

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NIH Grant Mechanisms

- **R01** Traditional investigator-initiated grant
  
  < $500K/yr, 3-5 yrs. Need approval if more than $500K for any year of the grant

- **R03** Small Grant
  
  < $100K for 2 yrs

- **R21** Exploratory/Developmental Grant
  
  < $275K for 2 yrs
Grant Purpose

- You want a grant to study what?
- Your key aims for the project are?
- What is the payoff to you & PH?
Probe – before you plunge.

Test the waters before you invest time and resources, or you risk getting soaked.

- Is NIH the right place to seek support?
- Does my project align with the institute’s mission?
- Is my study idea responsive to the RFA?
- Does my planned level of effort exceed the value of the problem I want to address?
- Do we have the talent and resources to succeed?
Develop Your Idea

- Review literature
- Generate preliminary data
- Enlist collaborators, include letters of commitment; Find collaborators and mentors who are experienced in writing and winning NIH grants
- Review successful grant applications of other colleagues
The “Top Ten” List

1. Read and re-read the program announcement
2. Assemble a strong research team
3. Use the strongest study design possible
4. If you have not been on a study section, confer with someone who has
5. Be sure to document the innovations
6. Document clear access to the study population
7. Make sure the writing, organization, & grammar are as tight as possible (write, re-write...read, re-read)
8. Seek reviews from experienced peers before submission
9. Make careful use of the summary statement
10. Persevere and don’t take rejection personally

(Source: Ross Brownson 1/13/2004)
Writing the Application

- Clear, concise writing style
- Be focused
- Don’t rush
- Critique, critique, and critique again
- Follow up with NIH program directors before and after review
Preparing the Application

- Follow instructions – PHS 398
- Never assume that reviewers “know what you mean”
- Refer to literature thoroughly; Present a clear rationale for the proposed work
- Make sure that the experimental approach is thorough and detailed
- Include well-designed tables and figures
- Anticipate human subject issues
R01 Research Grants

REVIEW CRITERIA:

- Significance
- Investigator
- Innovation
- Approach
- Environment

- Protection of Human Subjects
- Inclusion of Women, Minorities, Children
- Animal Welfare/Biohazards

Overall Evaluation & Score Reflects Impact on Field
Grant Review Criteria

- Significance: Does the study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced?

- Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated and appropriate to the project’s aims?

- Innovation: Does the project employ novel aims, concepts, approaches and methods?

- Investigator: Is the investigator appropriately trained?

- Environment: Does the scientific environment contribute to the probability of success?
Grant Review Criteria

- **Significance:** Does the study address an important problem or a critical barrier to progress in the field?
  
  - If the aims of the application are achieved, how will scientific knowledge, technical capability, and/or clinical progress be improved?
  
  - How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
Grant Review Criteria

- **Investigators:** Are the PD/Pis, collaborators, and other researchers well suited to the project?
  
  - If Early Stage Investigators or New Investigators, do they have appropriate experience and training?
  
  - If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
  
  - If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
Grant Review Criteria

- **Innovation:** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
  
  - Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
Grant Review Criteria

- **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

  - Are potential problems, alternative strategies, and benchmarks for success presented?

  - If the project is in early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

  - If the project involves clinical research are the plans for (1) protection of human subjects from research risks, and (2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
Environment: Will the scientific environment in which the work will be done contribute to the probability of success?

- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
1. **Specific Aims**
2. **Research Strategy**
   - Significance
   - Innovation
   - Approach
     - By each aim
     - Introductory paragraph
     - Justification and feasibility
     - Research Design, including type of data
     - Expected outcomes
     - Potential Problems and Alternative strategies
     - Preliminary studies for new applications
   - Timeline
   - Future Directions
Significance & Innovation

1. **Overall**: help justify the need for what is proposed
2. **Significance**: positive effect something is likely to have on other things
3. **Innovation**: a new and substantially different way of doing this, which results in positive change
4. **New Formats**: increase detail as the review reads further into the application
   a. **Does not begin with major literature review**
   b. **Strategically distributed among the different sections**
1. SIGNIFICANCE
   a. Does application address an important problem or critical barrier in the field
   b. If aims are achieved, how will scientific knowledge, clinical practice be improved
   c. How will successful completion of aims change the concepts, methods, treatments or preventive interventions that guide this field?
1. SIGNIFICANCE
   a. Part 1: critical analysis of literature with identified research gap (substantiate and validate problem)
   b. Part 2: *Statement of significance*
   c. Part 3: Discussion of benefits if aims completed
      i. Positive impact emphasis on the advance itself, and why relevant to NIH
1. INNOVATION
   a. Does application challenge and seek to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, etc.
   b. Is a refinement, improvement or new application of theoretical concepts, approaches or methodologies proposed?
1. INNOVATION
   a. Part 1: Document literature that will support a claim of innovation
   b. Part 2: “This project is innovative because....”
   c. Positive impact attributed to the substantive departure from the status quo that enabled the advancement
Problem / Background

Explain why the literature or your research leads you to think this topic needs study.

Any pilot info?

There are at least a dozen studies showing that drop-in clinic patients who drop out of treatment mention lack of staff concern as a contributing factor....
Significance

What is the payoff to science AND to public health?

Jones & Smith showed in their 2003 study that retaining drop-in clinic patients in treatment could save $1,100 per incident in reduced need for re-treatment and lowered contagion.
Question

Derived from the background literature, what model will guide your hypotheses and what hypotheses will you test?

I think that ASA theory will explain why patients will stay when service orientation is high, and what will re-engage patients who have left.
General Design Issues

- Will it work?
- Supporting preliminary data
- Valid Instruments
- Pilot data – very important
- Reality check – subject burden
- Will compliance rate(s) be adequate
Methodological Issues

- Sampling Methods
- Power Calculations
- Theoretically-based Intervention
- Data Acquisition and Management
- Data Analysis
Analyses

What statistical approach will ensure a fair test based on your data?

I want to run a lagged panel correlation and SEMs comparing dropouts, re-engagers, and stayers within and between clinics with SO training and without it.
Moderators Eat Up Power!
Application Tips from the trenches

- Make it readable (breaks between paragraphs, use clear transitions and headings and subheadings, number and bold the headings and subheads)

- Summarize at end of sections: what are the important gaps this application will address, what is the significance, what is the innovation – BE SHAMELESS HERE

- Aims and testable hypotheses: these aims/hypotheses should go from significance to measures to data analyses
Tips from the trenches (cont)

- Conceptual framework must be present and specific to this application; figures of models are useful as long as don’t have extraneous constructs

- Define key constructs with brief lit. review and make sure they are assessed specifically by the measures used

- Make sure that terms like mediators and moderators are used correctly

- If moderators are proposed, don’t just provide background on the main effects of the moderator variables on the outcomes
Tips from the trenches (cont)

- Make sure details are in agreement throughout (e.g. sample size, names of conditions..)

- Use multi-source, multi-method measures when possible

- Special attention to providing details in the Data Analytic section (examples, clear power estimates)

- Importance of the investigative TEAM
Team

Who do you envision as helping on the project?

- Disease experts
- MIS experts
- Statisticians
- Economists
- Field colleagues
- Theory consultants
Budget & Bios

- Helps reviewers determine if requested support is adequate to succeed.
  - **Overview expertise of key players.**
    - Introduce each team member & their role (1 para ea.)
    - Summarize the role of each consultant (1-2 sentences ea).
    - Describe significant supplies and travel (1 para ea.)
  - **Biosketches**
    - Include only relevant achievements and publications.
    - Summarize research support for each
      - Ensures people are not over extended or
      - Avoids paying twice for the same work.
Resources & Environment

- Helps reviewers learn about the setting and capabilities to carry out the study.
  - Research Computers
  - Research Office space
  - Clinic size, types of services, etc.
  - Linkages necessary to succeed
  - Access to information systems, etc.
Inclusion

To minimize health disparities:

- You must include:
  - Males & Females
  - Children (people 18-21 are also children)
  - Minorities

- If you cannot include all, explain why for each characteristic.

- Don’t forget to include a targeted enrollment table.
TIPS

- Have as many people review the final as time permits.
- Pick naïve reviewers – they ask the hardest questions.
- Run spell & grammar check.
- Remember:
  - Reviewers are smart, educated, sophisticated – BUT --
  - Reviewers not as familiar with your world as you are, so be sure to clearly describe your project and plans.
Keys To Success

- Recognize that NIH peer review has a special culture based on standing study sections composed of senior academic researchers with long histories of service and expectations of style, academic rigor, and hypothesis-based research.
“THAT’S IT? THAT’S PEER REVIEW?”
Initial Review (Peer Review)
SRA selects reviewers

Who are the Reviewers?
- They all have day jobs
- Active researchers
- Review applications in “spare time”
- Will review many applications; careful application preparation is valued
Most Common Problems

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient methodological detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions
Good Luck!

*If at first you don’t succeed –
Revise and resubmit*