Professional National Institutes of Health (NIH) Grant Development

FORMULAS FOR SUCCESS
Background

Dr. Mathilda (Tillie) Harris

- Director of Grant Training Center
- Has written successful grants for the past 25 years
- Assisted colleges and universities nationally and internationally to create cultures of grant procurement and increase their external funding
- Serves on many federal funding review panels
- Past positions:
  - Tenured faculty of Interdisciplinary Studies, Miami University (Oxford, OH)
  - Associate Vice President for the American Association of State Colleges and Universities (Washington, DC)
  - Associate Dean for the Graduate School of International Studies, University of Denver (Denver, CO)
General Grant Writing Concepts
Grant Writing for Success

10 things you must do

1. Start planning early
2. Develop your good idea
3. Use the NIH website (www.nih.gov)
4. Talk to your NIH Program Officer
5. Provide a good presentation
6. Provide solid literature review and preliminary data
7. Align with review criteria
8. Identify collaborators
9. Seek advice and feedback from colleagues
10. Understand funding and the peer review process
Start Planning Early

Pre-Submission Planning Timeline

- **PLANNING PHASE**
  - 8 months before receipt date
  - Assess yourself, your field, and your resources
  - Brainstorm; research your idea; call NIH program staff
  - Set up your own review committee; determine human and animal subject requirements

- **WRITING PHASE**
  - 7 months before receipt date
  - First outline your application’s structure; then write your application
  - Get feedback; edit and proofread

- **SUBMISSION PHASE**
  - 6 months before receipt date
  - Meet institutional deadlines
  - Receipt date

**Pre-Submission Planning Timeline**
call NIH
Where are you in your Career?

Approx. Stage of Research Training and Development

- GRADUATE/ MEDICAL STUDENT
  - Predoctoral Institutional Training Grant (T32)
  - Predoctoral Individual NRSA (F31)
  - Predoctoral Individual MD/PhD NRSA (F30)
  - Postdoctoral Institutional Training Grant (T32)
  - Postdoctoral Individual NRSA (F32)

- POST DOCTORAL
  - Mentored Research Scientist Development Award (K01)
  - Mentored Clinical Scientist Development Award (K08)
  - Mentored Patient-Oriented RCDA (K23)
  - Mentored Quantitative RCDA (K25)

- EARLY CAREER
  - Independent Scientist Award (K02)
  - Midcareer Investigator Award in Patient-Oriented Research (K24)

- MIDDLE CAREER

- SENIOR CAREER
  - Senior Scientist Award (K05)
What Constitutes Good Writing?

Manuscript vs. Grant Writing

Developing a business plan
Understanding the NIH
NIH Facts

- Provides ~90% of all federal support for the life sciences
- Provides nearly 90% of federal support of biological sciences
- Funds more than 82% of all federal psychology research
- Plays a relatively minor role for most other science disciplines
- A large supporter of social and behavioral sciences research
- Due to its budget ($39.1 billion in FY 18)
  - Accounts for two-thirds of all federal support for R&D in colleges and universities
Evolving Public Health Challenges

- Shift from Acute to Chronic Conditions
- Aging Population
- Health Disparities
- Emerging and Re-emerging Infectious Diseases
- Emerging Non-Communicable Diseases, e.g. Obesity
- Biodefense
NIH Actual Funding Levels for FY 2014-2018 (Billions)

FY 2014: 30.1
FY 2015: 31
FY 2016: 37
FY 2017: 33.1
FY 2018: 39.1
NIH Basics: Helpful Websites

NIH Grant Writing Tips

Applications and Forms

Application Receipt Dates
Why The RePORTer?

- Database of federally-supported biomedical research
- Access reports, data, analysis, expenditures
- Results of NIH-supported activities
  - Identify, analysis Institute research portfolios, funding patterns, and funded investigators
  - Identifies area and percentage of funding
  - Identifies PIs and their research
  - Identifies potential mentors/collaborators
The RePORTer
Institutes and Rosters

Office of Extramural Research
NIH Scientific Review Group (SRG) Roster Index

The initial step of the peer review process takes place in Scientific Review Groups (SRGs) that are managed by the Institutes and Centers that are components of the NIH. The Center for Scientific Review (CSR) is one of the NIH components that manage the scientific review groups that evaluate investigator-initiated applications. The CSR homepage provides a complete listing of Rosters for the Scientific Review Groups (SRGs) managed by CSR. The Awarding Institutes and Centers also manage many Scientific Review Groups that evaluate applications submitted in response to special solicitations such as Request for Applications (RFAs), and for unique programs. The listing below provides access to both membership rosters and meeting dates. Where available the subsequent links provide:

- The full name and complete description of each study section
- The name of the Scientific Review Officer (SRO) for each study section
- Scientific Review Group meeting schedules.

Special Emphasis Panels (SEPs) are listed by Institute or Center (IC). Within each IC there is an alphabetic listing of specific SEPs. The listing of the specific SEPs contains the roster for each SEP as well as contact information for the designated Scientific Review Officer.

Important Notice Of NIH Policy To All Applicants: All rosters are provided for information purposes only. Applicant investigators must not communicate directly with any review group member about an application either before or after the review. Failure to observe this policy strictly will create serious breaches of confidentiality and conflicts-of-interest in the peer review process. All questions must be directed to the Scientific Review Officer in charge of the review group. The roster below is a working document and should not be considered as complete until the meeting date. A final and complete roster will be provided with the summary statement.

AWARDING INSTITUTE AND CENTER STANDING COMMITTEE
ROSTER INDEX

<table>
<thead>
<tr>
<th>Roster Information</th>
<th>Committee Name</th>
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<tbody>
<tr>
<td>CSR</td>
<td>Center For Scientific Review CSR STANDING COMMITTEE</td>
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<tr>
<td>AA.1</td>
<td>NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM Biomedical Research Review Subcommittee</td>
</tr>
<tr>
<td>AA.2</td>
<td>NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM Epidemiology, Prevention and Behavior Research Review Subcommittee</td>
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<tr>
<td>AA.3</td>
<td>NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM Clinical, Treatment and Health Services Research Review Subcommittee</td>
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<tr>
<td>AA.4</td>
<td>NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM Neuroscience Review Subcommittee</td>
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<tr>
<td>AFNI</td>
<td>OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH Anatomical and Functional Mapping of the Internation of Major Internal Organs</td>
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<tr>
<td>AIDS</td>
<td>NATIONAL INSTITUTE OF ALLERGY AND INFECTIONS DISEASES Acquired Immunodeficiency Syndrome Research Review Committee</td>
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</tbody>
</table>
Knowing Your Reviewers: PubMed
Identifying NIH Initiatives
PA vs. RFA

- **RFA**
  - Targeted Research

- **Institute-Specific PA**
  - Research in a stated area of scientific interest

- **Parent PA**
  - Investigator-initiated research in any area

**narrow** to **broad**
Parent PA

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### Grants & Funding

**Parent Announcements (For Unsolicited or Investigator-Initiated Applications)**

NIH and other agencies serviced by eRA Commons want your investigator-initiated applications. Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA)**. We have developed Parent announcements for use by applicants who wish to submit what were formerly termed investigator-initiated or 'unsolicited' applications. Apply using the electronic application package for your chosen mechanism, listed in the table below. Read More About Parent Announcements. Not all Institutes and Centers participate in all FOAs. Please read announcements carefully to determine participation.

The following Parent Announcements are available (sorted by Activity Code):

**Research (R) | Research Training (T) | Career Development (K) | Fellowships (F) | Admin Supplements | Post-award Administrative Action**

#### Research (R) Announcements

<table>
<thead>
<tr>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
<th>Issuing Organization</th>
<th>Release Date</th>
<th>Opening Date</th>
<th>Expiration Date</th>
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<tr>
<td>R01</td>
<td>Research Project Grant (Parent R01)</td>
<td>PA-13-302</td>
<td>NIH</td>
<td>08/02/2013</td>
<td>08/07/2013</td>
<td>09/08/2015</td>
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<tr>
<td>R03</td>
<td>NIH Small Research Grant Program (Parent R03)</td>
<td>PA-13-304</td>
<td>NIH</td>
<td>08/02/2013</td>
<td>08/07/2013</td>
<td>09/08/2015</td>
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<tr>
<td>R13,U13</td>
<td>NIH Support for Conferences and Scientific Meetings (Parent R13,U13)</td>
<td>PA-13-347</td>
<td>NIH</td>
<td>09/11/2013</td>
<td>11/12/2013</td>
<td>09/08/2015</td>
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</tbody>
</table>

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What you should do

• Find the NIH program that *wants* to fund your proposal
• Seek your institute
• Find the roster of panel reviewers
• Go to PubMed to identify their publications
Funding Mechanisms
Support by Career Stage- M.D. Track

- T35: NRSA Short Term Institutional Research Training Grant
- T32: NRSA Institutional Research Training Grant
- F32: NRSA Individual Postdoctoral Fellowship
- K01: Mentored Research Scientist Development Award
- K08: Mentored Clinical Scientist Research Career Development Award
- K23: Mentored Patient-Oriented Research Career Development Award
- K24: Mid-Career Investigator Award in Patient-Oriented Research
- K22: Different names for this transition award
- K99/R00: Pathway to Independence Award
- K02: Independent Scientist Award
- F33: NRSA Senior Postdoctoral Fellowship

Award Types:
- T35
- T32
- F32
- K01
- K08
- K23
- K22
- K99/R00
- K02
- F33
- K24

Your Career Stage:
- High School Student
- Medical Student
- M.D.
- Clinical Training Phase
- Research Training Phase

Independent Investigator

Diversity Supplements

Faculty Position

Arlington, Virginia
granttrainingcenter.com
Support by Career Stage- Ph.D. Track

Award Types
- T32
- F32
- K01
- K22
- K99/R00
- K02
- F33

Your Career Stage
- High School Student
- Graduate Student
- Ph.D.
- Postdoc Phase
- Independent Investigator

Diversity Supplements

K99/R00
Training and Career Development Programs

NIH programs help to prepare the skilled, creative and diverse biomedical research workforce of tomorrow.

Recent Announcements
Health-professional Education Partnership Initiative (HEPI) (R25 Clinical Trial Not Allowed)

NIH Research Training and Career Development Programs
NIH programs help prepare individuals for careers in biomedical, behavioral, social, and clinical research.

CAREER DEVELOPMENT
KIDS

RESEARCH TRAINING
KIOSK
## NIH Grant Types

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>K</td>
<td>Mentored Jr. Faculty</td>
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<tr>
<td>R03</td>
<td>Pilot Study</td>
</tr>
<tr>
<td>R21</td>
<td>Small and Exploratory/Developmental Research Grants</td>
</tr>
<tr>
<td>RO1</td>
<td>Major research support</td>
</tr>
<tr>
<td>U01</td>
<td>Research Project Cooperative Agreement</td>
</tr>
<tr>
<td>U13</td>
<td>Principal Investigator Conference Grant</td>
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## NIH Grant Types

<table>
<thead>
<tr>
<th>Grant Type</th>
<th>Duration</th>
<th>Amount</th>
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<tbody>
<tr>
<td>K</td>
<td>4-5 yr</td>
<td>Up to $150k/yr</td>
</tr>
<tr>
<td>R03</td>
<td>2 yr</td>
<td>Up to $50/yr</td>
</tr>
<tr>
<td>R21</td>
<td>2 yr</td>
<td>Up to $175k/yr</td>
</tr>
<tr>
<td>RO1</td>
<td>4 yr</td>
<td>Typical $250K/yr</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can be &gt; $250K/yr*</td>
</tr>
<tr>
<td>U01</td>
<td></td>
<td>No specific dollar limit unless specified in FOA**</td>
</tr>
<tr>
<td>U13</td>
<td>1 yr</td>
<td>Varies</td>
</tr>
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*need permission if >$500K
** time varies
Career Development Awards (K-Awards)
Research Career Development Awards

To provide institutional research training opportunities (including international) to trainees at the undergraduate, graduate, and postdoctoral levels.

1. Select Role
   - Awardee
   - Appointee

2. Select Career Level
   - Select

Mentored Research Scientist Career Development Award

For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.

Details

FAQs

- When submitting a K99/R00 application which involves human subjects, do I need a study record for each phase?
- Who do I contact for questions about my specific application?
- If there are problems with eRA Commons registration or with the grants.gov submission process, where can one get help?
- Who do I contact for questions about my specific institutional training application or grant?
- Do Training Grants have pre-award cost authority?
- NIH uses a formula to calculate what would be awarded for tuition/fees and training related expenses on institutional training grants. Should the grantee use this formula as part of their requested budget in a
Review Criteria of K Awards

• Candidate
• Career Development Plan/Career Goals & Objectives
• Research Plan
• Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
• Environment & Institutional Commitment to the Candidate
K Award Orientation

FY 2018
• Payline for K Awards (except K99) based on a score of 20 or above

K99s
• NIAID only funds 6 applications per fiscal year among the 4 different chartered committees
• Very competitive

<table>
<thead>
<tr>
<th>NIAID 2017 Success Rates</th>
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<tbody>
<tr>
<td>K08</td>
</tr>
<tr>
<td>K01</td>
</tr>
<tr>
<td>K22</td>
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<td>K24</td>
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<tr>
<td>K25</td>
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<tr>
<td>K99</td>
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</table>

*4 applications were submitted
K Mentored Awards

K01 Mentored Research Scientist

K08 Mentored Clinical Scientist

K23 Mentored Patient-Oriented Research

K22 Career Transition Award
R03 Planning Grant
NIH Small Grant Program (R03)

Introduction
The R03 grant mechanism will support small research projects that can be carried out in a short period of time with limited resources. The NIH has standardized the Small Grant (R03) application characteristics, requirements, preparation, and review procedures in order to accommodate investigator-initiated (unsolicited) applications.

The R03 Parent Funding Opportunity Announcement (FOA) for investigator-initiated R03 applications can be found at PA-13-304 and articulates the policies and procedures that apply to this grant mechanism.

This website describes the use of the investigator-initiated R03 and describes the NIH Institutes and Centers (ICs) that intend to accept such applications.

Application Characteristics
- You may request a project period of up to two years and a budget for direct costs of up to two $25,000 modules or $50,000 per year.
- The R03 cannot be renewed.
- One resubmission (Ali) is allowed.
- Introduction required for a resubmission is limited to one page.
- No preliminary data are required but may be included if available.
- The Research Strategy may not exceed 6 pages.
- A doctoral student may not apply for an R03 grant to support thesis or dissertation research. An R03 award may be used to assist students who are pursuing dissertation studies when the work is within the scope of the R03 award.

Scope
The common characteristic of the small grant is the provision of limited funding for a short period of time. Examples of the types of projects that ICs support with the R03 include the following:

grants.nih.gov/grants/funding/r03.htm
NIH Exploratory/Developmental Research Grant Award (R21)

Introduction

The R21 grant mechanism is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development. The NIH has standardized the Exploratory/Developmental Grant (R21) application characteristics, requirements, preparation, and review procedures in order to accommodate investigator-initiated (unsolicited) grant applications.

The R21 Parent Funding Opportunity Announcement (FOA) for investigator-initiated R21 applications can be found at PA-18-489 and PA-18-344; and articulates the policies and procedures that apply to this grant mechanism.

This website describes the use of the R21 and describes the NIH Institutes and Centers (ICs) that intend to accept such applications.

Application Characteristics

- You may request a project period of up to two years.
- The combined budget for direct costs for the two year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.
- The R21 can not be renewed.
- No preliminary data are required but may be included if available.
- The Research Strategy may not exceed 6 pages.

Scope

- Exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications.
- 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, behavioral, or clinical research.
NIH Exploratory/Developmental Research Grant Award (R21)

- Encourages new, exploratory & developmental research projects
- Provides support for the early stages of project development
- Sometimes used for pilot & feasibility studies
- Limited to up to two years of funding
- Combined direct costs budget may not exceed $275,000
- Preliminary data generally not required
NIH Research Project Grant Program (R01)

Introduction
The Research Project Grant (R01) is the original and historically oldest grant mechanism used by NIH. The R01 provides support for health-related research and development based on the mission of the NIH. R01s can be investigator-initiated or can be solicited via a Request for Applications. This website is devoted to the investigator-initiated R01 application, which means there are no specific program requirements. However, the R01 research plan proposed by the applicant must be related to the stated program interests of one or more of the NIH Institutes and Centers based on their missions.

The Research Portfolio Online Reporting Tools (RePORT) website provides information about research grants including the number of funded new and competing R01s, average award dollars and characteristics of research project grants.

Definition of an R01
The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

Scope
The NIH is comprised of Institutes and Centers that support specific areas of health-related research and almost all Institutes and Centers at the NIH fund R01 grants. Research grant applications are assigned to an Institute or Center based on receipt and referral guidelines, and many applications are assigned to multiple Institutes and Centers as interdisciplinary and multidisciplinary research is encouraged.

Applicants are encouraged to identify a participating IC that supports their area of research via the R01 IC-Specific Scientific Interests and Contact website and contact Scientific/Research staff from relevant ICs to inquire about their interest in supporting the proposed research project.

For specific information about the mission of each NIH IC, visit the List of NIH Institutes, Centers, and Offices website.
NIH Research Project Grant Program (R01)

- Supports discrete, specified, circumscribed research projects
- NIH's most commonly used grant
- No specific dollar limit
  - Unless specified in FOA
- Advance permission required for $500K or more (direct costs) in any year
- Generally awarded for 3 -5 years
- Utilized by all ICs
Research Project Cooperative Agreement (U01)

• Supports discrete, specified, circumscribed projects performed by investigator(s) in an area representing their specific interests and competencies

• Used when substantial programmatic involvement is anticipated between the awarding Institute and Center

• One of many types of cooperative agreements

• No specific dollar limit unless specified in FOA
Principal Investigator Conference Grant (U13)

• A cooperative agreement award mechanism
• Principal Investigator retains the primary responsibility for planning, directing, & executing the proposed project
• NIH staff acts as a partner with the Principal Investigator
• The Institute/Center Conference Grant Contact or program staff should be contacted for further discussion
Specific Aims Page
Specific Aim Page

• A road map of your proposal
• Write your aims again and again and again...
• The single most important section
  • It’s the master plan for the rest of the proposal
  • First impressions are important to engage or lose the reviewers
• It’s the most difficult section to write
  • The logic of each aim must be compelling
  • Answers must be important to the field
• Write aims that you are excited about!
**Structure of a Specific Aim**

**Short introductory paragraph**
- Brief overview of project
- Significance
- Central hypothesis or goal

**Specific Aims**
- Descriptive one-line title
- Key preliminary data supporting hypothesis
- Experimental approach
  - How you will test the hypothesis
- Summary sentence
  - Why this experiment is important
Specific Aims - Examples

Okay

Specific Aim 1: To test the hypothesis that neurons in the GluR1 knockout mouse will have delayed dendritic maturation.

Better

Specific Aim 1: To test the hypothesis that GluR1 signaling is necessary for dendritic maturation (or is sufficient).
Examples of Specific Aims

“Define the spectrum of mitochondrial derangements in humans with diabetes and their relationship to endothelial dysfunction.”

“To identify independent predictors of progression to acute lung injury and establish a clinical definition of early ALI.”

“To determine the prognostic value of biological markers of inflammation and lung injury in identifying progression to acute lung injury.”
Making Your Case

Why must the work be done?
• Summarizing the state of the art
• Identifying critical gaps
• Proposing next logical step

Why is this PI & team the most qualified group to do the work?
• Establishing and documenting a track record
• Demonstrating expertise needed to perform the work
• Documenting a strong collaborative relationship
Example of a Specific Aims Page
Specific Aims

An objective/aim must be SMART
• **S**pecific
• **M**easurable
• **A**ttainable
• **R**ealistic
• **T**ime-bound

**Should contain no more than three objectives/aims**
• Unless otherwise stated in the RFA
Specific Aims Page

1st paragraph: broad, long-term goal of research
• Arresting opening w/relevance to health
• Background that addresses long-term goal
• Current knowledge
• Gap in knowledge/importance of filling gap

2nd paragraph: objective of the application
• Objective of application to achieve long-term goal
• Background that addresses objective of application
• Central hypothesis
• Rationale
• Investigators/environment
Specific Aims Page (cont.)

3rd paragraph: specific aims
• Aims should be related but not interdependent
• Each aim has a clear goal & is measurable, specific, & attainable
• Each aim has a working hypothesis or hypotheses

4th paragraph
• Expected outcomes—organized around aims
• Innovation statements
• Relevance to public health or mission of institute
• Other benefit/impact statements
Specific Aims: Paragraph 1

Opening Sentence(s)
• Highlight significance

Important Knowns
• Explain the current situation & set the scene for presenting the gap

Addressing the Gap
• Sentence that articulates how research will advance the field

Framing the Gap as a Problem
• Show how this gap prevents the field from advancing
• Make sure goal is to know something specific
Specific Aims: Paragraph 2

Long-Term Goal
• Define continuum of your research and a clear linkage between this project and the gap you are trying to fill

Objective
• Explanation of what will be accomplished & its relationship to the long-term goal
  • Example of a poorly stated objective: “Our objective in this application is to study the effects of sexual violence on women’s psychological health.”
  • Don’t use terms like: study, explore, better understand… as they convey indeterminate endpoints
  • Use terms such as determine, develop, test, analyze
Specific Aims: Paragraph 2

Central hypothesis
• Must be testable

Rationale
• Explain how this research advances the field
  • This is the underlying reason you choose to pursue this project
  • Must relate to the critical need and mission of funding agency

Research team & environment
• Explanation on qualifications of the team to conduct this research
Specific Aims: Paragraph 3

• List your Aims here

• There should be a hypothesis for each aim

• Describe how hypothesis will be tested
  • Avoid technical details

• Convince the reviewer that the aim will be accomplished
Specific Aims: Paragraph 4

Innovation
• Make the case for why research is innovative

Expected Outcomes
• What are the expected outcomes of your study?

Impact
• How are expected outcomes going to have a positive impact once the acquired knowledge from your research is applied?
Examples of Applicants’ Submitted Specific Aims
Basics of Writing a Grant (K, R03, R21, R01, & U01 series)
What to Focus on First

• “So What” Question and SOW
• Significance
• Hypothesis
• Goal
• Objectives (aims)
• Methods and Approach
• Collaboration
Standard Format

Specific aims (1 page)

- Defining the long & short-term goal
- Outline of aims 1, 2, & 3, etc.

Research Strategy

a. Significance (paragraph)
b. Innovation (paragraph)
c. Approach (few pages with preliminary data)
d. Research design & methods with potential pitfall & alternative approaches & timelines
Scope of Work

Should consist of carefully worded statements that answer:

• What is to be done?
• What are the deliverables?
• Who is going to do it?
• When is it going to be done?
• How will it be done?
• How can you tell when it is done?
• How much will it cost?
Research Strategy-NIH

(a) Significance

• Importance of the problem that the project addresses
• How will the proposed project improve:
  • Scientific knowledge, technical capability, and/or clinical practice in one or more broad fields
• How will these change if the proposed aims are achieved:
  • Concepts, methods, technologies, treatments, services, or preventative interventions
Research Strategy-NIH

(b) Innovation

• How the application challenges & seeks to shift current research or clinical practice paradigms

• Novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used

• Any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions
Research Strategy-NIH

(c) Approach

• Description of the overall strategy, methodology, & analyses to accomplish the specific aims
  • Include how the data will be collected, analyzed, & interpreted as well as any resource sharing plans

• Discussion of potential problems, alternative strategies, & benchmarks for success anticipated to achieve the aims

• If the project is in the early stages of development
  • Describe any strategy to establish feasibility & address the management of any high risk aspects

• Point out procedures, situations, or materials that may be hazardous to personnel and proposed precautions
Principal Investigator

Is the principal 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 researchers, if any?
Environment

Does the environment in which the work will be done contribute to the probability of success?

Does the research take advantage of unique features of the environment or employ useful collaborative arrangements?

Is there evidence of institutional support?
Literature Review

• Integrate throughout the application
• Your literature should be highly selective
• Discuss publication strengths & weaknesses in the Significance subsection
• Cite primary literature, not reviews
• Cite references using author and year, not numerals
• Use your published work to support feasibility
Preliminary Studies

- Included to support scientific premise or technical feasibility
  - Under significance or approach

- Preliminary data strengths and weaknesses
  - Must be discussed

- Different mechanisms require different amounts of preliminary data

- Always include them
  - Even if there is wording that they are not needed
Preliminary Studies (cont.)

• Early stage investigators need less preliminary data than established researchers

• Do not include unpublished work in support of feasibility
  • Data presented must establish feasibility in your hands

• Presentation of preliminary data should be organized to make one point and one point only
Preliminary Studies (cont.)

Write in a way that leads reviewers through the data

• Do not make reviewers interpret what you meant

Include a fully italicized sentence at the end of the paragraph

• Will show reviewers why what you presented supports feasibility in your hands
Bibliography and References Cited

- Should be primary literature, not reviews
- Present in alphabetical order
- Number or use hanging-indent format
  - Without a separating open line
- Should be up-to-date
- Be consistent
- Books and other documents should have page numbers
- Don’t reference anything that would be difficult for reviewers to find
  - E.g. conference proceeding
Approach

Timeline and Benchmarks
• Prepare a timetable
• Clearly mark each benchmark
• Demonstrate progress

Future Directions
• Conclude with a paragraph that speaks to future directions
  • Give it a title that reflects this
• If writing a K, R03 or R21
  • Use this section to demonstrate progress to an R01
Budget
Budget Justification

Purpose
• Helps answer the question
  • Is the bang worth the buck?

What is it?
• Provides rationale for all budget requests
  • On & off-campus personnel, equipment, supplies, travel, rent, etc.
• No Page Limit
• Must be credible in the experience of the reviewers
Direct Costs

Participant Support Costs

- Reimbursement for participating in training
  - Per diem
  - Travel costs
  - Registration fees
  - Participant allowance
- Non-academic employees

Payments to Subjects
CVs
NIH Biosketch

A. Personal Statement
   • Briefly describe why your experience & qualifications make you particularly well-suited for your role in the project

B. Positions and Honors

C. Contribution to Science
   • Briefly describe up to five of your most significant contributions to science

D. Research Support
   • List both selected ongoing & completed (during the last three years) research projects (Federal or non-Federal support)
   • Begin with projects most relevant to current research
A. Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. As PI or co-investigator on several university-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have a demonstrated record of accomplished and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.
Biosketch Sample
Reviewing and Scoring
Part 1: Review Criteria
Review Criteria

• Must assess *all* scoreable items

• Except for Significance
  • Emphasis placed on each item at your discretion

• **You must be consistent in your approach**
  • e.g. deciding which should be weighted more heavily than others

• There are distinct differences between reviews
Applications must be Judged on these Five Criteria:

1. **Significance**
   Importance of the problem, potential impact on the field

2. **Approach**
   Experimental design, pitfalls, and alternatives

3. **Innovation**
   Originality and novelty of the concepts, challenge to dogma

4. **Investigator**
   Training, experience, integration of the team

5. **Environment**
   Institutional resources, uniqueness of subject populations
Non-Scoreable Items

The following are often mistaken for review criteria

- You must address them separately from scoreable items
  - Budget
  - Biohazards
  - Data Sharing Plan
  - Model Organism Sharing Plan
  - Foreign Institution
Peer Review Criteria for Various Awards

Definitions of Criteria and Considerations for K Critiques

Review Criteria at a Glance
Reviewing and Scoring
Part 2: Scoring and Streamlining
Scoring Guidelines

• Scores go to one decimal place
• The range is 1.0 (best) to 9.0 (worst)
• Preliminary scores of the ad-hoc reviewers may change if swayed by co-reviewers' posted critiques
<table>
<thead>
<tr>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Minor Weakness: An easily addressable weakness that does not substantially lessen impact  
Moderate Weakness: A weakness that lessens impact  
Major Weakness: A weakness that severely limits impact
## 9-Point Score Chart

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
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</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td></td>
</tr>
</tbody>
</table>

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed
Example of NIH peer review process

(online video)
Master the Techniques of Writing Superior & Winning Proposals

By following the discussed procedures, you can master the techniques of writing superior and winning proposals

Thank-you