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Mahidol University
Wisdom of the Land

Faculty of Tropical Medicine
Mahidol University

How to Write An International (NIH) Grant

Mahidol University
March 12, 2020

Contents

- Introduction to funding opportunities and review processes

- MUST know
  - How to write a competitive grant?
  - Revision and resubmission
  - Discussion

Experience: Grant Writing (>$30 million in funding)

- NIH : R01 (2+), R21 (3*), U01 (1), U19 (2), D43 (2*)
- US-DoD (> 20)
- Wellcome Trust (2+)
- Bill & Melinda Gates Foundation (BMGF)
- TDR grant from WHO (2)

Why Do We Need Research Grants?

- Gain new knowledge
- Expand your research
- Capacity building
- Career advancement
  - Salary support
  - Promotions


Some may call it……
Writing an international grant is like diving into the unknown

As an international scholar, you are not disadvantaged!

- Apply to the category that suits you
- New vs. experienced investigators:

  - New investigator (NIH): anyone who has not served as the PI for any major NIH grants (e.g., R01)
  - Reviewers will evaluate applications of new investigators differently from those of experienced applicants
  - Almost all reviewers want new investigators to do well in the review process

NIH Grant Cycles

Applicant Initiates Research Idea

Conducts Research

University Submits Application

Electronic Submission

GRANTS.GOV

National Institutes of Health

Assign to Institute and Study Section

center for scientific review

Peer Review

1st NIH Study Section 1946

Review of Scientific Merit

Institute
(24 with funding authority)

Evaluate Relevance

Leaders in the biological and medical sciences, education, health care, and public affairs.

Advisory Council

Recommend Action

Institute Director

Takes Action

Allocation of Funds

NIH Funding Opportunities

U.S. Department of Health & Human Services

www.hhs.gov

National Institutes of Health

The Nation's Medical Research Agency

Employee Info | Staff Directory | En Español

search

>> Advanced Search

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- NIH at a Glance
- Training at NIH
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Funding for Research

- » Grant Application Basics
- » Forms
- » Deadlines
- » Funding Plans by Institute
- » Award Information & Data

Search Funding Opportunities

search

Removing barriers for women in biomedical research careers

more information

▶ 1 2 3 4 5

Health Information

For A-Z in consumer health topics, visit Health.nih.gov.

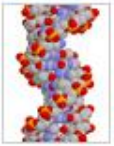
Clinical Trials

For info about clinical research in volunteers, visit clinicaltrials.gov.

Research Highlights

Review our collection of Research Results for the Public.

Biotechnology



National Center for Bio Info nat mo info

In The News

Metabolic Syndrome
Greater incidence of metabolic syndrome among adults consuming soft drinks

ADHD Treatment
Improvement following ADHD treatment sustained in most children

» For the Press

» eColumn: NIH Research Matters

NIH RADIO PODCASTS

Medical Research Initiatives

www.nih.gov

HEALTH	GRANTS	NEWS	RESEARCH	INSTITUTES	ABOUT NIH
A to Z Health Topics	Grants & Funding	News Releases	Training	Office of the Director	Mission
Clinical Trials	Funding Opportunities (NIH Guide)	Calendar	Intramural Research	27 Institutes and Centers that make up the NIH	From Our Director
MedlinePlus	Forms and Deadlines	Media Contacts	Human Embryonic Stem Cell Registry		Visitor's Info
Health Hotlines	Electronic Research Admin (eRA)	For the Press	Scientific Interests Groups		Organizational Structure
	Grants Policy	NIH Record	Labs		Budget
	News & Events	News In Health newsletter	Library Catalog		History
		Research Matters eColumn	Journals		Science Education
		RSS			Public Involvement

Internet 100%

U.S.Department of Health & Human Services www.hhs.gov

Office of Extramural Research
National Institutes of Health

Contact Us | Print Version
Search: Go
Advanced Search | Site Map

Home | About Grants | Funding | Forms & Deadlines | Grants Policy | News & Events | About OER

About Grants

Grants Process & Data

- Grant Application Basics
- Grants Process Overview
- Types of Grant Programs
- How to Apply
- Peer Review Process
- Award Management
- NIH Financial Operations (w/Funding Strategies)
- Award Information & Data

Electronic Grants

- Electronic Research Admin (eRA Commons)
- Applying Electronically

Funding

Funding Opportunities

Search Funding Opportunities:
NIH Guide for Grants and Contracts
Go

- Funding Opportunities (RFAs, PAs) & Notices
- Unsolicited Applications (Parent Announcements)

- Research Training & Career Development
- Small Business (SBIR/STTR)
- Contract Opportunities

NIH-Wide Initiatives

- New Investigators Program
- Multiple Principal Investigators
- Genome-Wide Association Studies (GWAS)
- NIH Roadmap for Medical Research
- NIH Blueprint for Neuroscience Research

Global OER Resources

- Glossary & Acronyms
- Frequently Used Links
- Frequent Questions

News & Events

News Flashes

OER Grants Web Site Redesigned to provide a new look and feel with new and updated content.

More News...

Get Connected

- NIH Extramural Nexus
- NIH Guide LISTSERV
- SBIR/STTR LISTSERV
- Animal Welfare (OLAW) LISTSERV
- eSubmission News

Workshops & Seminars

NIH Regional Seminar on Program Funding and Grants Administration

- San Antonio, TX (3/08)
- Chicago, IL (6/08)

More Workshop Info...

Selected Policy Notices

Grants Policy

- Policy & Guidance
- Compliance & Oversight
- Research Involving Human Subjects
- Animal Research (OLAW)
- Peer Revie
- Intellectual
- Invention R

Forms & Deadlines

- Forms & Applications
- Submission Dates / Deadlines
- Submitting Your Application

About OER

- OER and You
- Staff Directories & Organizational Charts
- Visiting NIH
- Contact Us

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Report
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October 1, 2007

grants1.nih.gov/grants/oer.htm

Internet 100%

NIH OER: NIH Guide for Grants and Contracts

Research Portfolio Online Reporting Tool (RePORT)

- A searchable database of federally supported biomedical research
- Access reports, data, analyses, expenditures, results of NIH supported research activities

- Identify, analyze IC research portfolios, funding patterns, funded investigators:
  - Identify areas with many or few funded projects
  - Identify NIH-funded investigators and their research
  - Identify potential mentors/collaborators

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NIH RePORTer

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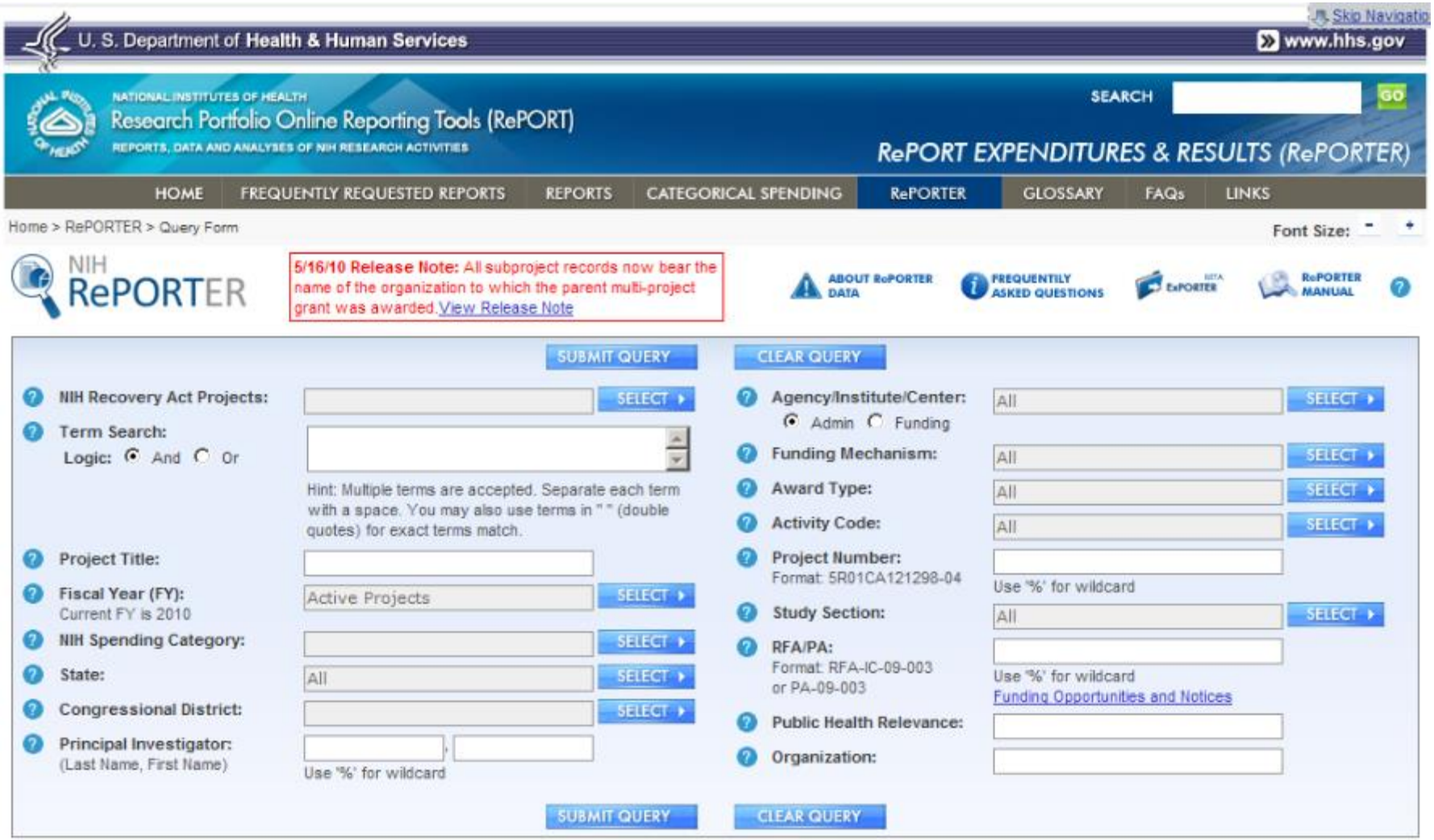
Mahidol University



http://projectreporter.nih.gov/reporter.cfm

Are You Eligible?

Individual

- From graduate students to senior investigators
- Citizenship requirement for some but not others
- Special criteria for new and early stage investigators

Institutional

- Domestic, foreign, private, public, non-profit, for-profit are eligible to receive NIH funds with restrictions depending on the funding mechanism

International Grants - requirements

Just because you are eligible to apply for a specific grant does not mean you should apply for it!

Funding Mechanisms for International Investigators?

- Foreign investigators can apply for NIH funding directly (R series), but not for NSF funding
- International investigators can receive funding through subcontracts from US universities
- NIH has specific programs for foreign PIs

NIH Standard R Grants

R01 Research Project Grant (funding for up to 5 years, normally $250K direct cost per year, but up to $500K is allowed without prior permission)

R21 Exploratory/Developmental Research Grant (exploratory studies, funding for 2 years, total $275K direct cost, limited preliminary data is required)

R03 Small Research Grant Program (funding for 2 years, $50K direct cost per year, only requires limited preliminary data)

R13 Support for Conferences and Scientific Meetings

Special Programs (PA, RFA)

- Tropical Medicine Research Centers TMRC (U19)

https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-16-002.html

- International Research in Infectious Diseases, including AIDS (R01)

https://grants.nih.gov/grants/guide/pa-files/PAR-17-142.html

Tropical Medicine Research Centers TMRC (U19)

- NIH funded 8 centers in 6 countries
- Last rounds of TMRC supports research on single or multiple pathogens of the following NTDs:
  - Schistosomiasis, hookworm infection, ascariasis, leishmaniasis, trypanosomiasis, Chagas' Disease, trichuriasis, leprosy, lymphatic filariasis, trachoma, onchocerciasis, dracunculiasis, Buruli ulcer, echinococcosis, taeniasis and cysticercosis, and food-borne trematodiases
- Annual budget up to $500,000 (direct cost), 8% indirect cost rates
- Total support period 5 years
- Normally funds 6-8 proposals per round
- Next competition should be in 2020

International Research in Infectious Diseases, including AIDS (R01)

- NIAID funded
- The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
- Annual budget up to $125,000 (direct cost), 8% indirect cost rates
- Total support period 5 years
- Foreign PIs from resource-constrained countries
- Awarded every year

Planning Your Application EARLY

Grants Process & Data
Grant Application Basics
Grants Process Overview
Types of Grant Programs
How to Apply
Peer Review Process
Award Management
NIH Financial Operations
Award Information & Data

Electronic Grants
Electronic Research Admin (eRA Commons)
Applying Electronically

Global OER Resources
Glossary & Acronyms
Frequently Used Links
Frequent Questions

Grant Writing Tips Sheets

Many NIH Institutes put out guides and tip sheets on their Web sites. These guides can be useful resources. Here are just a few.

- All About Grants - Including Grant Application Basics, How to Plan a Grant Application and How to Write a Grant Application.
- Applying for an NHGRI Grant
- Choosing an Appropriate NIH Funding Instrument and Funding Mechanism (MS Word - 209 KB)
- NIH Grants Information CD (PDF - 51 KB)
- Peer Review Guidelines and Information
- Peer Review Meetings - Meeting dates, descriptions, rosters, guidelines, etc.
- Preparing Grant Applications
- Quick Guide for Grant Applications
- Quick Guide for the Preparation of Grant Applications (Complementary and Alternative Medicine)
- SBIR/STTR Policy and Grantsmanship Information
- Tips for New NIH Grant Applicants
- Writing a Grant

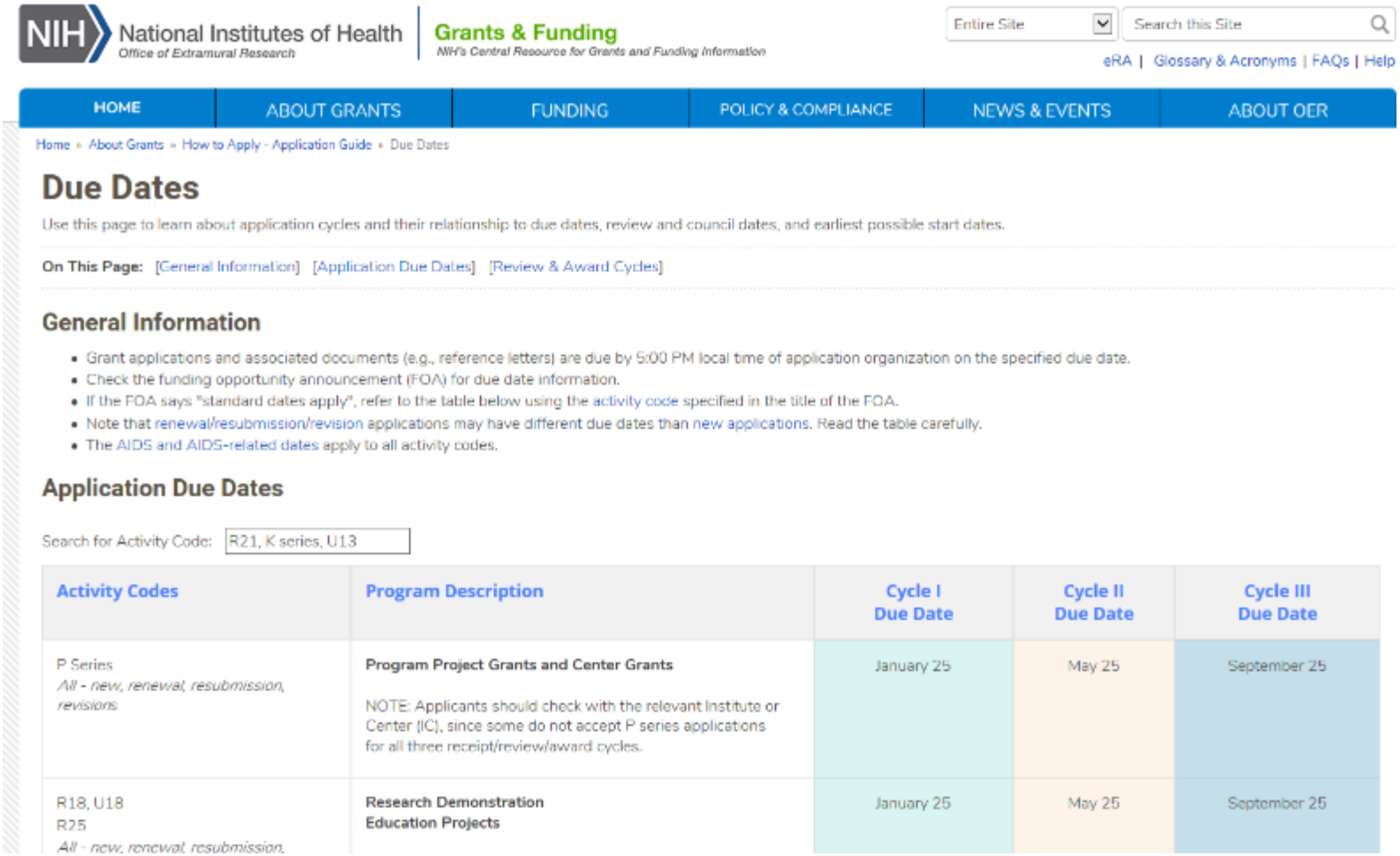
Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint or RealPlayer files, see Help Downloading Files.

grants1.nih.gov/grants/grant_tips.htm

Observe the Due Dates

Standard due dates:

https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm



NIH National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

Entire Site | Search this Site

eRA | Glossary & Acronyms | FAQs | Help

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER

Home » About Grants » How to Apply - Application Guide » Due Dates

Due Dates

Use this page to learn about application cycles and their relationship to due dates, review and council dates, and earliest possible start dates.

On This Page: [General Information] [Application Due Dates] [Review & Award Cycles]

General Information

- Grant applications and associated documents (e.g., reference letters) are due by 5:00 PM local time of application organization on the specified due date.
- Check the funding opportunity announcement (FOA) for due date information.
- If the FOA says "standard dates apply", refer to the table below using the activity code specified in the title of the FOA.
- Note that renewal/resubmission/revision applications may have different due dates than new applications. Read the table carefully.
- The AIDS and AIDS-related dates apply to all activity codes.

Application Due Dates

Search for Activity Code: R21, K series, U13

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
P Series *All - new, renewal, resubmission, revisions*	**Program Project Grants and Center Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.	January 25	May 25	September 25
R18, U18 R25 *All - new, renewal, resubmission,*	**Research Demonstration Education Projects**	January 25	May 25	September 25

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Standard Due Dates

Activity Code	Program Description	Cycle 1	Cycle 2	Cycle 3
R01 new	Research Grants	February 5	June 5	October 5
U01 new	Research Grants	February 5	June 5	October 5
R03, R21 new	Research Grants	February 16	June 16	October 16
R01 renewal, resubmission, revision	Research Grants	March 5	July 5	November 5
U01 renewal, resubmission, revision	Research Grants	March 5	July 5	November 5
R03, R21 renewal, resubmission, revision	Research Grants	March 16	July 16	November 16
R13, U13 All	Conference grants	April 12	August 12	December 12

Source of Guidance

- Mentor (current and/or proposed)
- University/School Sponsored Programs Office
- Other colleagues & faculty
- RePORTER database online
- NIH Program Staff (before applying and after review)

Critical Steps Before Starting the Application

- Agency Priorities
  - Examining RFAs and PAs
  - Go to the Web Site!
  - Talk to a Program Officer
    - Telephone Conversations
    - Brief Proposals
  - Talk to Colleagues Who May Be in the Know!

Understand How NIH Peer Review Works – who are the reviewers?

- Established Investigators - few assistant professors
- Demonstrated scientific expertise
- Mature judgment
- Breadth of perspective
- Impartiality
- Adequate representation of women and minority scientists
- Diversity of expertise represented

Peer Review: Evaluation Criteria

- NIH standard review criteria
  - Significance
  - Investigator
  - Innovation
  - Approach
  - Environment
- Also initiative specific review criteria, when applicable
- Different criteria for training related applications

How Your Proposal Will Be Reviewed?

- Understand the tendencies and roles of the readers
  - All will hear the Abstract
  - Some will read the Specific Aims
  - Fewer still will skim the application
  - Assigned reviewers will read it all
  - Stats expert on the committee will have an interest in analysis

New NIH Scoring System

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Other Review Considerations

- Human subjects
- Animal care and use
- Select agents
- Model organism sharing plan
- Data sharing plan
- The FOA will list the review criteria and any additional issues that reviewers will be asked to evaluate.

Considerations Prior to Starting the Application

- What you should consider “in your hour of darkness”
  - Can I do this?
  - Am I willing to commit to this project that required energy necessary to make it a success?
  - Do I have the support needed to pull this off?
  - Are needed institutional logistic support there?

- A grant application is not created only to get money, but to help you do better work once you have been funded!

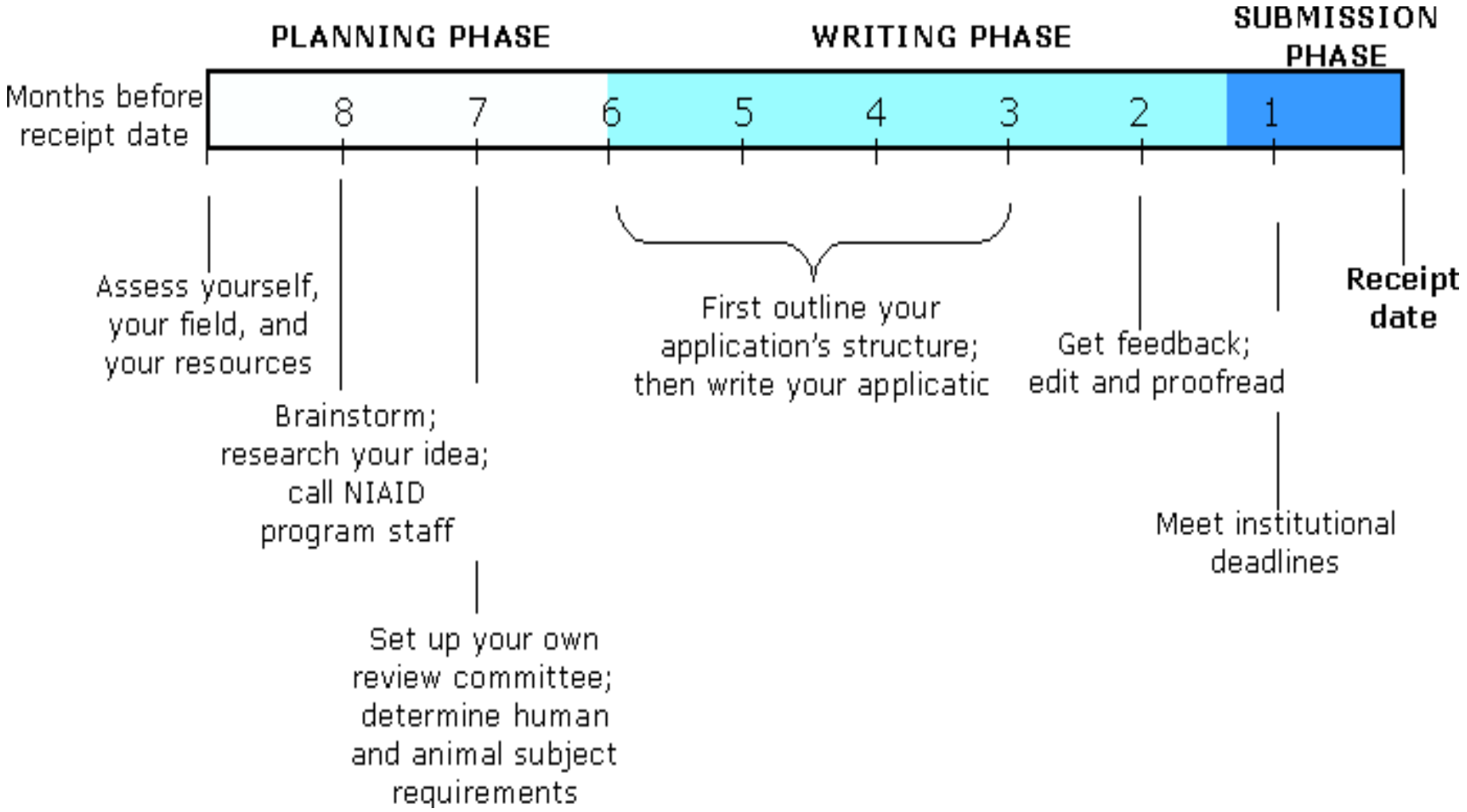
Institutional Submission System Is Ready ??

- eRA Commons: secure web-based information exchange between NIH and applicant organization (PI and Business Official) http://commons.era.nih.gov
- Applicant business office and PI must establish personal eRA Commons accounts to track review progress and to retrieve scores and summary statements

Moving Forward: General Suggestions

- Allow 3 months to write the grant
- Read the Published Instructions and follow them to the letter
- Read and re-read your research plan after it is complete
- Give the final draft to outside readers for review
  - Specialists
  - Generalists
  - Methodologists/Statisticians

Pre-Submission Planning Timeline

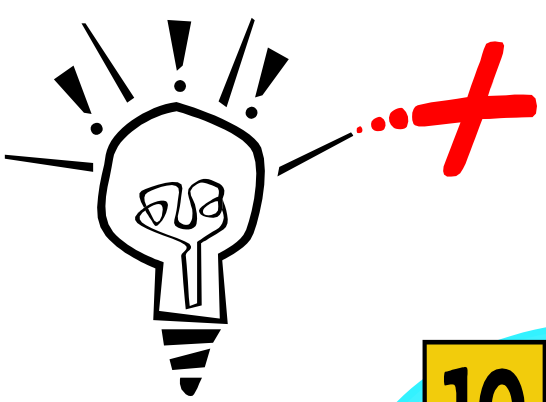


Most Common Reasons for Unsuccessful Applications

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

Formula for Successful Applications

Idea + **Communication** + **Presentation**



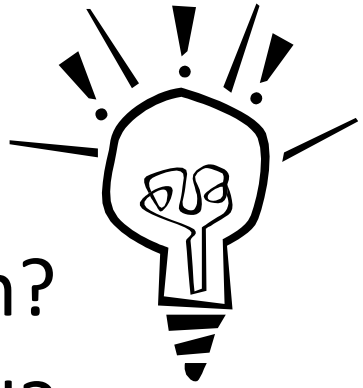
+

MUST Know for Writing NIH proposal

Steps to A Successful Grant

- Start planning EARLY
- Read solicitations carefully (www.nih.gov)
- Determine whether it fits your research
- Talk to your NIH Program Official(s)
- Develop your good idea
- Identify collaborators
- Provide a good presentation
- Align with review criteria
- Ask comments from your colleagues

Start with A Good Idea

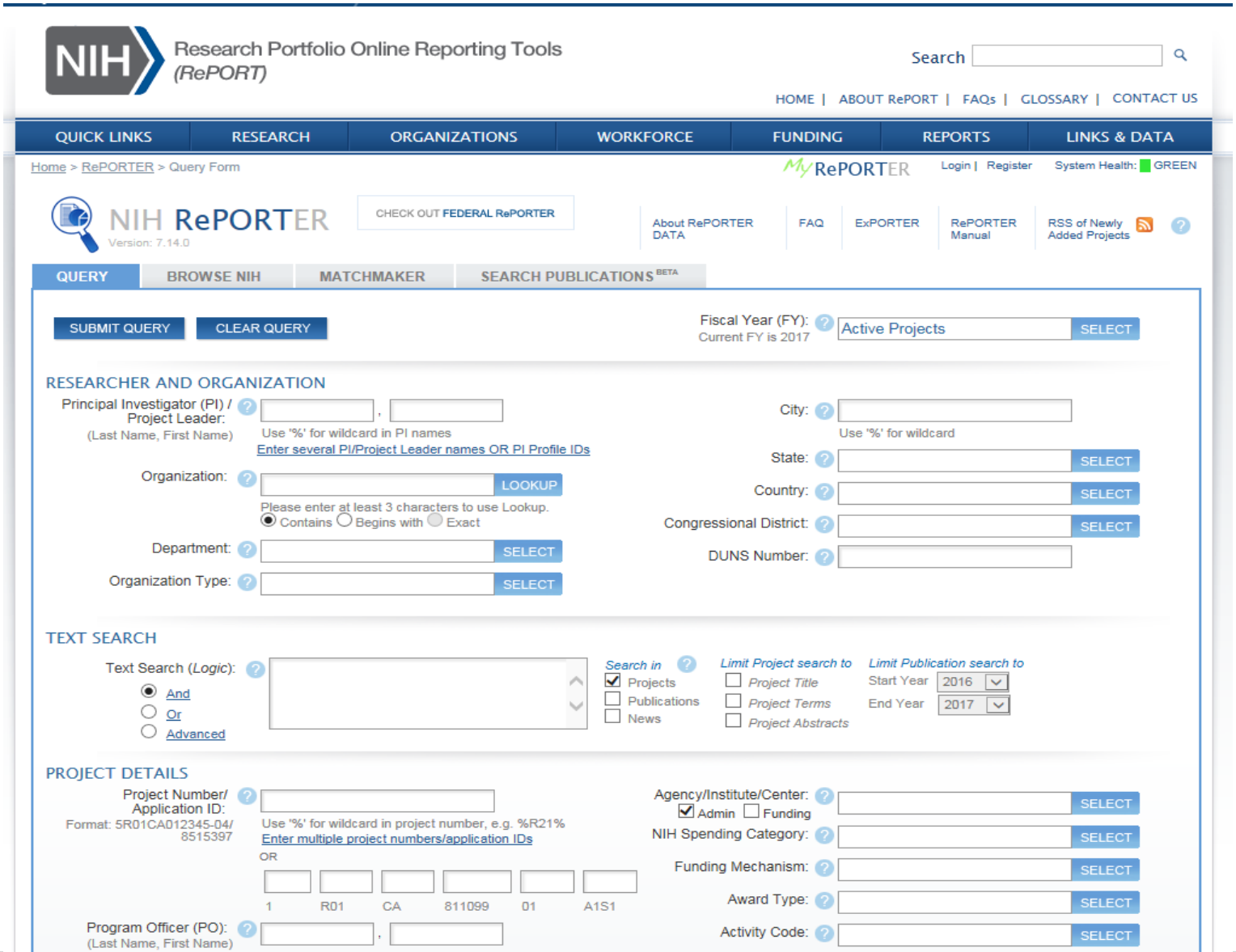


- Does it address an important problem?
- Will scientific knowledge be advanced?
- Does it build upon or expand current knowledge?
- Is it feasible …
  - to implement?
  - to investigate?

How to Develop A Good Idea

- Define the problem that you want to address
- Collect and critically analyze background information that pertains to your investigation
- Generate a preliminary idea: you find it significant, can you convince others of this fact?
- How to assess your idea's potential for success?
  - Your own ability to pursue the idea
  - Assess your competition – other people may have similarly good ideas (home work)
- Seek constructive criticism from knowledgeable colleagues
- Refine your idea to maximize its impact

Are Similar Ideas Funded by NIH
NIH RePORTER System



Remember and Align Your Proposal with the Five Criteria of the Review

- Significance
- Investigator
- Innovation
- Approach
- Environment

Successful Grant Applications Will Convince Reviewers That:

- Your proposal addresses an important questions in basic or applied sciences
- Your research plan will answer these questions in an efficient and convincing way
- You know the contemporary “relevant” literature in your field, *as well as its limits*
- Your study address these limits

Successful Grant Applications Will Convince Reviewers That:

- You have the expertise to execute the plan outlined—simply put, you and your team are the best people in the world to do the project!

- You have access to everything you need (equipment, subjects, reagents, etc.) to execute the plan and have budgeted appropriately

Successful Grant Applications Will Convince Reviewers That:

- You will analyze your data in a thoughtful and honest way with sufficient power to find effects
- You will disseminate your findings in a timely manner
- You will accomplish your experimental plan in the time requested and with the amount of money requested

Writing!!

Research Plan: Sections

- Abstract
- Specific Aims
- Research Strategy
  - Significance
  - Innovation
  - Approach
  - Preliminary studies
  - Progress report (for renewal and revision)
- Appendices*

Title and Abstract

- Title
  - Capture essence of goals and objectives
- Abstract
  - Present your project Concisely
  - State significance Clearly
  - State Hypotheses, Research Problem, Solution
  - Methods and Rationale

Specific Aims – 1 page

- Critical section; may be the only part of your application reviewers will read or have read to them! Write them first and revise them last
- Introduce problem you are addressing, with minimal background to orient all readers
- Make your aims stand out clearly
- Introduce aims of project, followed by specific hypotheses to be tested
- Briefly describe main techniques you will use to answer questions
- Outline experimental plan
- Describe the advance this study represents

Hypothesis-Driven Research

- Most good research is hypothesis-driven
- Science moves forward in incremental steps; convince reviewers that your study is the evolution of what has come before
- The hypotheses you state here are revisited and operationalized in the Research and Design Section
- Don’t assume your hypotheses are correct—this is a fatal error!

Research Strategy: Significance

- Use this section to convince the reader you have command of the literature *and its limitations*
- Remain focused on the issues your experiment will address; in other words, how will your experiment resolve important issues in the field
- Significance section should be thoughtful, but brief. Convey why this research is important and its public health importance, particularly with applied work

Innovation

- Describe the novelty of this work in
  - *Concepts (potentially paradigm-changing)*
  - *Technology (new technology)*
  - *Methods (e.g., systems approach)*

Preliminary Studies

- How previous work -- by you, your team, and others -- leads to this study
- Demonstrate your experience (hopefully published) with most of the experimental techniques in the investigation – experience and feasibility
- Demonstrate your experience, competence and likelihood of continued success
- Publish your work in the rigorous journals of your field; reviewers attend to this as a yardstick of the standard you set for yourself
- Present results of *your work, even if it is in its preliminary stages!*

Preliminary Studies

- After application is submitted and before study section meets:
  - Continue to work on all preliminary studies
  - Submit final report on the pilot work you are doing to the study section secretary, who will pass it along to the reviewers
  - Attempt to have a manuscript under review by the time the study section meets

Needs for Collaboration

- Collaborate with other investigators
  - Fill gaps in your expertise and training
  - Add critical skills to your team
- "Team Science" is the new direction
  - Support for multidisciplinary research projects
  - Consider the Multiple-PI Model
- Need a strong team to support new investigators

Investigators and Team

- Who are the members and what expertise do they bring?
- How do the skills of the team compliment each other?
- Highlight previous experience as a team if it exists
- Spend time to work on the biosketch of each investigator (new format)

Biosketch (5 pages)

- Personal Statement – why experience and qualifications make the applicant particularly well-suited for role in the project
  - List up to 4 most relevant publications
- Contribution to science
  - Divide by fields
  - List 4 most relevant publications in each field
    - Complete List of Published Work in MyBibliography (myNCBI)

Approach

- Propose only experiments that directly test the hypotheses you propose
- Don't propose more than your laboratory can do in the allotted time – don't be "too ambitious"
- Make sure that what you are proposing to do is state-of-the-art in all respects – "innovation"
- Design an efficient set of experiments

Approach: Components

- Overview of procedures
- Description of alternatives and why you decided to use the methods you chose
- Acknowledge pitfalls of what you propose
- Description of measures and all other materials you need to address components of your hypotheses
- Data management

Approach: Components

- Overview of methods with timetable
- Description of subjects – Human Subjects
  - Inclusion and exclusions
  - Recruitment plan (feasibility)
  - Women, minority, and children inclusion
- Recruitment is often a central component of feasibility—can you realistically get the number of subjects you propose?

Approach: Components

- Data Analysis Section
  - Provided and overview for state-of-the-art data analysis sections
- Revisit Specific Project Aims (Hypotheses)
  - Explore various analytic methods to be used to examine generated data
  - Discuss missing data issues and how they will be handled

Approach: Components

- Power analysis – sample size justification
- Critical section for many applications and is often the section in which applications fail
- Do you have enough statistical power to find effects?
  - This should drive how much data you are collecting and the size and scope of your project

Revising……..

- Ask a colleague to review your draft
  - Ask a colleague who does not already know what you intend to do
  - Ask a colleague who is not your best friend
- Your draft reviewers need to understand
  - What you intend to do
  - Why you believe it is important to do
  - Exactly how you are going to do it
- **Leave enough time to make revisions**

Literature cited

- Include all authors, title, journal, year, volume and pages
- Make sure it is complete: cite all mentioned in the proposal
- Make sure the format is consistent (use software such as EndNote to manage the references)

Letters of Support

- Questions are typically too complicated to be successfully answered by one investigator
- Teams are assembled to answer questions
- Assemble a team whose members complement each other
- Obtain letters that provide specific information about what they will do

Environment

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
- Is there evidence of institutional support?

  Facilities

  Equipment

Appendices

- Publications that are discussed in the Background and Significance and Preliminary Studies Sections *that are yours and/or those of other investigators on your team*
- Treatment manuals
- Measures
- Informed Consent Documents

Presentation Style:

Prepare A Reviewer-friendly Application

- Be well organized and clear
- Format: make it reader-friendly
- Use fonts large enough
- Divide sections, add section headings
- Make headings and subheading clear
- Spelling and grammar – important
- Figures and tables – easy to read and appealing

Budget Preparation

Budgets: Five Precepts

- The research plan and budget must describe the same project and be mutually reinforcing
- The budget must be sufficient to accomplish the aims of the project
- The budget must be realistic and reasonable
- Costs are time dependent
- Fully justify each proposed cost (budget justification page)

Costs: Two Very Different Types

- Direct Costs
  - Those which you budget and can spend on your project
- Indirect Costs (F&A costs)
  - Reimbursed to the University for institutional expenditures to support all externally funded projects (international grants typically has a 8% F&A cost)

Thresholds: Are you over either?

- Will your total direct costs exceed $500 thousand in any single year?
  - If so you must obtain Program Officer approval six weeks prior to submission.

- Will your total direct costs exceed $250 thousand in any single year?
  - If so you must submit a detailed budget.

Thresholds: If you are over neither

- You must submit a modular budget request
  - Unless the program announcement says otherwise

- You should use the detailed budget format to work up your budget before converting to modules

What Are modules?

- NIH awards most research grants in fixed increments of $25K
- Each such fixed increment is a module
- Up to 10 modules ($250K) may be requested
- If the direct cost request will not exceed $25k, only the number of modules requested is required and a detailed budget will not be accepted

Budget Building Block : Direct Cost Categories

- Salaries and Wages
  - Name, title, appointment type, project effort, base salary, requested salary for each *employee* who will work on the project
- Fringe Benefits
  - Computed by multiplying the S/W cost by the appropriate benefit rate
- Consultant Costs
  - Name, approximate number of days and total cost; cost should be inclusive of per diem, travel (if any), etc.

Budget Building Blocks cont'd.

- Equipment
  - Is any tangible property costing $5k and having a useful life of more than one year
  - List each item individually and describe fully in the budget justification
  - Include vendor and cost

- Supplies
  - Breakdown into major categories, e.g. chemicals, animals, survey forms, software application packages, etc.
  - Justification should detail how total cost for each category was computed

Budget Building Blocks cont'd.

- Travel
  - Purpose and cost
  - Justification should include person(s) traveling, purpose of trip, mode and cost of transportation, number of days in travel status and per diem

- Patient Care Costs
  - Provide generic descriptor of treatment on either in or out patient line
  - Justification should include all components of therapy and cost of each, hospital/clinic where treatment will be provided, basis for treatment cost, any contribution to total cost of therapy provided by another source.

Budget Building Blocks cont'd.

- Alterations and Renovations
  - Necessary to make essential interior space useable by the project or to facilitate installation of essential equipment
- Consortium/Contractual Costs
  - Cost of funding collaborators at other Institutions who will conduct part of the project
  - Each collaborating institution must provide a letter committing to participating in the project at the cost indicated in the proposal, a detailed budget, and a research plan (scope of work) for the part of the project which it will perform

Budget Building Blocks cont'd.

- Other Direct Costs
  - Costs not covered by the categories listed above: Tuition, Publication costs, vehicle fuel and maintenance, animal care, human subject fees

Total Direct Cost and Modified Total Direct Cost

- Total Direct Cost (TDC) is the sum of all of the costs listed in the direct cost categories.
- Modified Total Direct Cost is TDC *less*
  - Equipment
  - Tuition
  - Patient Care
  - Subcontract costs exceeding $25k
  - Fellowships/Scholarships
  - Alt./Renovation
  - Off-campus space rental

Grant Review and Revision

What the Summary Statement Will Look Like?

- Reviewers use a structured template
  - Reviewers provide bulleted comments for:
  - Overall strengths & weaknesses
  - Strengths & weaknesses of each core criterion
  - Comments on Other Review Considerations
- Additional comments (“advice” to applicant)
- Goal: increase transparency of review process and to improve feedback provided to applicants

Example

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
Malla Rao
301-451-3749
mrao@niaid.nih.gov

Release Date: 11/08/2012

Application Number: 1 R01 AI104822-01

Principal Investigator

PRACHUMSRI, JETSUMON PHD

Applicant Organization: MAHIDOL UNIVERSITY

Review Group: ZRG1 IDM-R (50)
Center for Scientific Review Special Emphasis Panel
PAR11-145: International Research in Infectious Diseases including AIDS (IRIDA)
AIDS - EXP. REV.
Meeting Date: 10/10/2012 ***RFA/PA:*** PAR11-145
Council: JAN 2013 ***PCC:*** M90
Requested Start: 05/01/2013

Project Title: Discovery & validation of novel P. vivax antigens for identification and monitori

SRG Action: Impact Score: 36
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 5A-Only foreign subjects, scientifically acceptable
Children: 1A-Both Children and Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	125,000	134,440
2	125,000	134,440
3	125,000	134,440
4	125,000	134,440
5	125,000	134,440
TOTAL	625,000	672,200

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

Not Discussed?

- What about Not Discussed Applications?
- Applications that are not discussed by the review panel:
  - Are generally those in the lower half
  - Do not receive an overall impact score
  - Receive summary statements that include the written critiques and criterion scores from the assigned reviewers but do not include an overall impact score

How to Approach a Negative Review

- Give yourself the time and space to feel sad and angry, but appreciate that your colleagues, students, lab members are watching
- Avoid calling or writing your program officer until you have calmed down
- Then read the reviewer's comments CAREFULLY
- You will need to decide whether or not the reviewers show any enthusiasm for your application
- Talk with:
  - A senior scientist with experience reading critiques
  - Your program officer

Remember……

Reviewers are never wrong

Reviewers are never right

They simply provide an assessment of material that you provided in your application

Don’t Take the Criticism Personally!

Revisions: Part of the Process

- You will likely have to revise your initial submission; less than 1 in 10 applications are funded the first time through

- When you get your summary, read them carefully
  - Look at the score and determine what it means for your institute and study section
  - Determine if the reviewers have any enthusiasm for your application
  - If you decide to revise, respond explicitly to each criticism

The Revised Application

- Your are given 1 introductory page to highlight the criticisms and how you responded to them

- Make the changes readily apparent in the application to readers…
  - Highlight, bold, italicize changes in the body of the application

Top 10 Common Reviewer Concerns

…..or How Not To Get DINGED!

There is not a CLEAR HYPOTHESIS, or WELL DEFINED GOALS

- Provide a focused hypothesis, objectives
- Describe the importance and relevance of your problem
- Be clear on how your project will move the field forward

The specific aims do NOT TEST the Hypothesis, or the specific aims DEPEND on results from previous aims

- The best proposals are those with independent specific aims that address your hypothesis using different approaches

The proposal is NOT MECHANISTIC, or NOT SCIENTIFICALLY RELEVANT

- Do not propose correlative studies, propose strong associations
- Do not propose general observations, propose specific manipulations

This application is not APPROPRIATE for the GRANT MECHANISM

- A R21 is NOT a R01
- A Career Development Award (K) is NOT a Research Project Grant (R)

The proposal is

OVERLY AMBITIOUS

- Set realistic goals for the budget and project period you propose

PRELIMINARY DATA is lacking

- Include preliminary data for all aims
- Use preliminary data to show knowledge of methods and data analyses
- But DO propose more than just confirming preliminary results

I'm not sure that the Investigator can do the PROPOSED EXPERIMENTS

- Don't propose what you can't do
- Include Collaborators and Consultants on your project
- Describe the value of datasets and experimental models

The background section is MISSING KEY publications and experimental findings

- Thoroughly describe the literature, especially controversies, *but….*
  - Support your views and ideas
  - Be sure you have found key references

Experimental details, alternative approaches, or interpretation of data are INADEQUATELY DESCRIBED

- Don’t assume the reviewers know the methods
- Provide other experimental directions you might use should you encounter problems
- Show the reviewers that you have thought about your research plan

The Proposal is NOT RELEVANT to the MISSION of the Institute

- Make your application FIT the Mission of a particular Institute
- Don’t FORCE your application on an Inappropriate Institute

Revise and Resubmit

- Properly Revised applications can receive fundable scores and subsequent $$
  - Score can inform degree of revision necessary
- Update Preliminary Results
- Maintain communications with Scientific Review Officer and Program Official

Notice NOT-OD-14-074: NIH and AHRQ Announce Updated Policy for Application Submission

Revising and Resubmitting

- Write A Clear Introduction Section
- Address All Criticisms Thoroughly
- Respond Constructively
- Acknowledge and Accept the Help of Reviewer Comments
- Don't Be Argumentative!
- Don't be Abrasive or Sarcastic!

Responding to Reviewer Comments

Q: What if you know that you are "Right" and the reviewers are "Wrong", is it appropriate to argue your position in your resubmission

A: NO!

Remember:

- An application for funding is not about the facts of your completed research.
- It is about ideas and potential research
- DO NOT be Argumentative !
- DO NOT be Abrasive !
- DO NOT do long-term damage to yourself

Revise and Resubmit

Prepare a REVISION COVER LETTER

- For Revisions, Indicate Review History
- Request Same Or Different Study Section
- Provide Justification for your request
- Don't be Argumentative ! Never!
- Don't be Abrasive ! Never!

Persistence Pays

- You are given three submissions for a given application
- Less than 20% of first applications are funded
- About 30% of second submissions are funded
- About 38% of third submissions are funded