

Developing an NIH R01 Proposal: Tips, Strategies for Success



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Today's Outline

- “Mechanics” of the NIH grant development & review process
- Components of a proposal
- Review criteria/process
- Tips for Success!



Why?????



- An expectation for academic research faculty in many fields
- Helps to develop and sustain your own research program- research costs \$\$!
- Contribution to science, impacts on public health.

Who Funds Research?

- Federal Government
 - Health and Human Services
- Foundations
 - Independent
 - Corporate
 - Community
- Others
 - Health Plans
 - Research Institutes



Federal Government Grants



Food and Drug Administration
USDA
Centers for Disease Control
Agency for Healthcare Research and Quality
And.....the National Institutes of Health

NIH: “Turning Discovery into Health”



NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

The National Institutes of Health

- National Institute of Allergy and Infectious Disease
- National Cancer Institute
- National Heart, Lung, and Blood Institute
- National Institute of Diabetes and Digestive and Kidney Diseases
- National Institute on Aging
- National Institute of Child Health
- National Institute of Mental Health
- Others (27 institutes)



The National Institutes of Health

Funding Mechanisms

- Research Project Grants (**RO1**), Others:
 - R21: exploratory/developmental research grant; 2 years; \$275,000 direct costs (total)
 - R03: small grants program; 2 years; \$50,000/yr direct costs; not offered by all institutes
- Program Project Grants (P)
- Training Grants (T,F [NRSA]), Career Development Grants (K series)
- Cooperative Agreement Grants (U)

R01

- Most commonly used NIH grant program
- *Usually* \$500,000/yr in direct costs
- 3-5 years
- Used to support a particular project
- Can be submitted in response to a particular RFA (focused topic area, \$ set aside) or in response to a PA (general topic/theme)
 - Sample: PA-10-152 Diet Composition and EB
 - “Generic”: PA-10-064

Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (<http://www.nih.gov>)

Components of Participating Organizations
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (<http://www2.niddk.nih.gov>)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), (<http://www.nichd.nih.gov/>)
National Cancer Institute (NCI), (<http://www.nci.nih.gov/>)
National Center for Complementary and Alternative Medicine (NCCAM), (<http://nccam.nih.gov/>)
National Heart, Lung and Blood Institute (NHLBI), (<http://www.nhlbi.nih.gov/index.htm>)
National Institute on Aging (NIA), (<http://www.nia.nih.gov/>)
National Institute on Alcohol Abuse and Alcoholism (NIAAA), (<http://www.niaaa.nih.gov/>)
Office of Dietary Supplements (ODS), (<http://ods.od.nih.gov>)

Title: Diet Composition and Energy Balance (R01)

Announcement Type

This is a reissue of [PA-07-218](#).

Update: The following updates relating to this announcement have been issued:

- [September 29, 2010](#) (NOT-OD-11-007) - NIH to Require Use of Updated Electronic Application Forms in 2011. Adobe B1 forms are required for due dates on or after September 29, 2010.
- [August 16, 2010](#) - IMPORTANT NOTE! NIH has eliminated the error correction window for due dates of January 25, 2011 and beyond. As of January 25, all corrections to applications must be submitted by the [GRANTS 2010-10-100](#).

Investigator Initiated Application (e.g., R01)



Hmmm.....water and weight loss....

- Requires a good, unique idea
(...Significant, Innovative);
- Investigator(s) must have expertise... and...
- Institution must have resources
- Resources for proposal ideas?
 - HP 2020 document
 - Search funding opps (NIH site)
 - NIH CRISP, RePorter

After you have an idea: Planning the Project

- Choose the funding agency, mechanism
- Seek collaborators and supporters
 - Need a good team!
- Review the PHS 398/SF424 Application Form
- Assemble the research team
 - Are the “dots connected”?
- Develop a timeline
- 3-6 months (or more) to prepare the application
- ?Pilot data (demonstrates support for your ideas/aims, feasibility)



The Application Process

- NIH Center for Scientific Review receives application
 - Often 6-8 months for review process.
- Initial peer review and scoring: Review panel
 - Scores posted within 1-2 weeks of meeting
 - PI receives summary statement after review
 - 6-8 wks
 - *Generally* know your fate at this point
- Second-level review
- Institute or agency decides which applications will be funded



The Review Criteria: Handout

- Significance – ability to improve health?
- Approach – feasibility/appropriateness of methods
- Innovation – originality
- Investigator (s) – training and experience
- Environment – suitable, supportive?

Overall Impact

The Basic Components of a Proposal

- The proposal summary
- The background/problem statement, and Aims (1 page)
- Research Strategy:
 - Significance
 - Innovation
 - Approach
- The project budget, justification
- Biosketches
- Facilities, Human Subjects, Others....



The Proposal Summary or Abstract

- Should be concise
- Serves as the cornerstone of the application
- May determine whether the proposal is reviewed by the Review Group
- May be the only part of the application most reviewers read
- Should be written last!



Statement of the Problem: Relevant background information leading to the Aims (1 page, with Aims)

- The purpose for developing the proposal
- Who will benefit and how
- The nature of the problem and its social and economic costs
- The current management of the problem
- Future implications of the project;
 - impact on the research field



Drafting Aims.....

- Have a good idea!
- Is it unique, original?
 - Know the literature, questions, controversies
 - NIH RePORTER, CRISP
- **Solicit feedback early in the process!**
- Propose to solve a particular problem, challenge an existing paradigm or clinical practice, address a knowledge “gap”
- Ask: Important impact? Significance?
- Aims reflect the outcome of the project
- Aims should be succinct and evaluable
- Can the aims be accomplished with the proposed time & resources?
- Adequate preliminary data?

The Research Strategy

- Overall:
 - Organize to correspond with aims—in a logical sequence
 - Write concisely; make one point in each paragraph.
 - Use subheadings, short paragraphs, bullets, numbered lists, bold key concepts.
 - Include figures, diagrams
 - Cite references whenever possible



The Research Strategy: Significance

- Explain how the project address an important problem or a critical barrier to progress in the field
- Explain how the project will advance knowledge, or improve clinical practice
- Make the case – why should NIH fund your research?
- **Sell your idea!**



The Research Strategy: Innovation

- Is the project/idea novel?
- Does it challenge/shift current research or clinical practice paradigms by using novel theoretical concepts, approaches, methodologies, or interventions?
- Does it refine or improve theoretical concepts, approaches, methodologies, or interventions?
- Does it address an unresolved issue, controversy?



The Research Strategy: Approach

- Describe methods, analyses used to accomplish aims
- Discuss potential problems, alternative strategies
- Are the methods proposed appropriate to achieve the stated aims?
- Examples.....
 - Method to assess abdominal/visceral fat?
 - Method to deliver a low-sodium diet intervention?

The Organization, Facilities and Environment



Resources of organization

- Clinical staff
- Analysts
- Computer equipment
- Office space
- Support staff
- Appropriate study subjects - examples

Previous research success of the research team and PI

Human Subjects Research

- The application must include
 - Plan to protect subjects from research risks
 - Plans to include women, children, minorities
 - Data and safety monitoring plans
 - Benefits to subjects and public health



Human Subjects Research

- Review criteria also include
 - Plans to recruit and retain subjects, e.g. women and minorities
 - Reasonableness of proposed budget and duration in relation to the proposed study
 - Adequacy of proposed protection of humans, animals, or the environment if they may be adversely affected by the research
 - Adequacy of the plan to share data

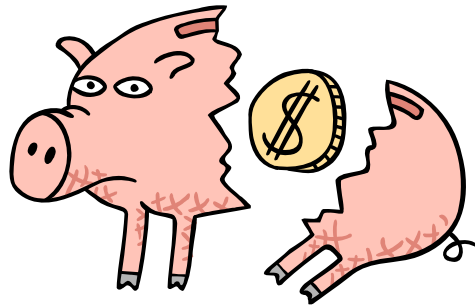
Human Subjects

- Grant Applications proposing research with human subjects must be reviewed and approved by the Institutional Review Board prior to release of the award.



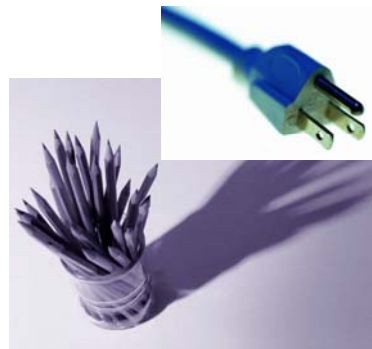
Budget, Justification

- Direct Costs
- Personnel
- Consultants
- Equipment
- Supplies
- Travel
- Patient Care Costs
- Other Expenses



Facilities and Administration Costs

- “Indirect Cost Rate” is negotiated by the grantee institution with HHS
- Costs that cannot be readily identified with an individual project
 - Fringe benefits
 - Overhead
 - General and Administrative
 - At VT?



Success Rates Vary

- New Investigators
- Training grants
- Institutes
- Two Shots



Tips for Success!

- Seek mentoring
- Seek feedback early in the process– aims page
 - Senior colleagues
 - NIH program officers
- Have good preliminary data
- Enlist good collaborators (your team)
 - Statistics expertise
 - Consultants
 - Co-investigators with expertise you don't have, but need



Tips for Success!

- Look at successful proposals, if you can!
- Start well before your deadline – don't rush...
 - Revise, revise, revise
- Know the literature, controversies
- Show the feasibility, timeline
 - Overly ambitious?
- Potentials pitfalls, alternative strategies
 - How will anticipated problems be overcome?



Tips for Success!

- Present the best possible end product:
 - clear organization, whitespace, figures
 - NO typos, sloppy formatting
- Have others read your final draft; seek feedback
 - NOT the week before the grant is due.....
- If you are not in the money....revise carefully and address all issues raised.
 - Share your summary statements with others
 - Read between the lines....?



Hang in there!!

