## Winning More Grants!

Best Tactics for use on New NIH Short Form

Karin Rodland
Chief Scientist for NIH Programs
Pacific Northwest National Laboratory



Principal Investigators Association<sup>™</sup>

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#### **Winning More Grants!**

#### **Best Tactics for use on New NIH Short Form**

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March 31, 2010

#### **Topics**

- Changes to NIH Grant Application Procedures
- Restructured Application Forms
- Alignment of Application with Review Criteria
- ► Impact and how to write for it

Enhancing Peer Review Overview and Timeline

January 2009 May/June 2009

January 25, 2010 Submissions

- Phase out of A2s
- Identification of Early Stage Investigator (ESI) applications
- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Clustering of new inv.
   Applications
- Score order review

- Alignment of applications & review criteria
- ShorterResearch Plans

#### **CRITICAL Communications to Applicants**

For all receipt dates January 25, 2010 and beyond:

Need to download and use new application forms (available by December 2009)

- URL: <a href="http://grants.nih.gov/grants/funding/424/index.htm#">http://grants.nih.gov/grants/funding/424/index.htm#</a> inst
- Paper and Electronic

Need to be aware of new instructions

- New page limit requirements
- Restructured applications

#### **Direct from the NIH:**

- These changes apply to all competing applications, so whether you are submitting a new, renewal, resubmission or revision, you must take action now to ensure a successful submission!
  - 1. Return to the updated funding opportunity announcement or reissued parent announcement < <a href="http://grants1.nih.gov/grants/guide/parent\_announcements.htm">http://grants1.nih.gov/grants/guide/parent\_announcements.htm</a>> to download the new application package and instructions.
  - FOAs are in the process of being updated. See timeline < <a href="http://enhancing-peer-review.nih.gov/parent\_announcements.html">http://enhancing-peer-review.nih.gov/parent\_announcements.html</a> for more information.
  - 2. Be sure to choose the correct forms. Applications intended for due dates on or after January 25 require new forms.
  - For Electronic SF 424 (R&R): ADOBE-FORMS-B
  - For Paper PHS 398: Revision date "June 2009"
  - 3. Read the updated FOA and new application instructions carefully

For more details the Enhancing Peer Review Web site which has a page dedicated to the upcoming application changes <a href="http://enhancing-peer-review.nih.gov/restructured\_applications.html">http://enhancing-peer-review.nih.gov/restructured\_applications.html</a>, as well as a number of additional resources including:

- A short video overview < <a href="http://enhancing-peer-review.nih.gov/application\_changes\_video.html">http://enhancing-peer-review.nih.gov/application\_changes\_video.html</a> of the changes
- FAQs < http://enhancing-peer-review.nih.gov/faqs.html>
- List of related policy notices < <a href="http://enhancing-peer-review.nih.gov/policy\_announcements.html">http://enhancing-peer-review.nih.gov/policy\_announcements.html</a>>
- A Training and Communications Resources <a href="http://enhancing-peer-review.nih.gov/training\_communication.html">http://enhancing-peer-review.nih.gov/training\_communication.html</a> page, and more.

#### Biographical Sketch

- Personal Statement why experience and qualifications make the applicant particularly well-suited for role in the project
- Publications encouraged to limit to 15
  - 5 most recent
  - 5 best
  - 5 most relevant to the application

#### Restructured Research Plan

Introduction

Specific Aims

Background and Significance

Preliminary Studies/Progress Report

Research Design and Methods

**Inclusion Enrollment Report** 

Progress Report Publication List

Human Subjects Sections....

protections, women/minorities, enrollment, children

Other Research Plan Sections....

animals, select agent, MPI, consortium, support, sharing

**Appendix** 

Research Strategy

#### **Facilities and Other Resources**

(in SF-424 part of the R&R Other Project Information; in PHS-398 the Resources Format Page)

**Environment** - New instruction to address how scientific environment will contribute to probability of success, unique features of environment, etc. For early stage investigators, provide description of institutional investment in success of the investigator.

### Alignment of Application with Review Criteria

Core Review Criteria

**Application** 

Significance	Research Strategy	
	a. Significance	
Investigator(s)	Biosketch	
	Personal Statement	
Innovation	Research Strategy	
	b. Innovation	
Approach	Research Strategy	
	c. Approach	
Environment	Resources	
	Environment	

#### 5.5.1 Introduction (Resubmission or Revision Applications only)

See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA.

The Introduction is limited to one page unless specified otherwise in the FOA.

#### 5.5.2 Specific Aims

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Specific Aims are limited to one page.

#### 5.5.3 Research Strategy [NEW]

Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References cited section (Item 5.5.5). Follow the page limits for the Research Strategy in the Table of Page Limits, unless specified otherwise in the FOA.

#### (a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

#### 5.5.3. Background and Significance [OLD]

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. Two to three pages are recommended.

#### (b) Innovation [NEW]

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions

#### 5.5.3 Research Strategy [NEW]

#### (c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in 5.5.11 below.

Preliminary Studies for New Applications. For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application. Except for Exploratory/Development Grants (R21, R33), Small Research Grants (R03), Academic Research Enhancement Award (AREA) Grants (R15), and Phase I Small Business Research Grants (R41/R43), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data. (However, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in applications from Early Stage Investigators than on the preliminary data in applications from more established investigators.)

Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in 5.5.5; do not include that information here.

#### 4.4 Resources [NEW]

This information is used to assess the capability of the organizational resources available to perform the effort proposed.

- Identify the facilities to be used (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.
- Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

#### **Environment**

- For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.
- If there are multiple performance sites, describe the resources available at each site.
- Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research).

#### **Biographical Sketch**

Following the educational block, complete sections A, B, C and D:

A.Personal statement. Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application.

B. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit\_process\_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix materials).

D. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

#### Shorter Research Strategy

Page limits:

Introduction to Resubmission or Revision – all Activity Codes*	1
Specific Aims – all Activity Codes*	1
Research Strategy R03, R13, U13, R21, R36, SC2, SC3, R41and R43	6
Research Strategy R01, R15, R18, U18, R33, R21/R33, R34, U34, DP3, G08, G11, G13, UH2/UH3, SC1, R42 and R44	12
Research Strategy – all other Activity Codes	see FOA
Combined Candidate Information and Research Strategy (K)	12
Program Plan (K12, Kirschstein, R25)	25
Biographical Sketch	4

<sup>\*</sup> Except training (T)

#### What is Impact?

#### And how can I get some?

#### **Straight from the NIH:**

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

**Overall Impact:** Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field involved, in consideration of the five core review criteria.

#### What is Impact?

#### And how can I get some?

#### **Put Another Way:**

**For Significance**: Assume that *all the experiments work* – then how important will the results be?

#### Is the research worth doing?

**Overall Impact:** This includes the likelihood that the experiments will actually be successful.

### If it won't work, it won't have any impact, even if the problem has high significance!

Each Reviewer will weigh the individual core criteria differently in coming up with an assessment of Overall Impact

- there is no magic formula

#### Writing for Impact

Imagine yourself in an elevator with Bill Gates

You have 3 minutes to convince him your idea is worth

funding –

Can you do it?



FACT: Successful biotech entrepreneurs practice this 'elevator speech'!

#### **First Impressions Count!**

- Most reviewers make up their minds in the first page
  !
- Then they read the rest of proposal looking for support of their original opinion
- ► The meat is in the First Page
  - everything else is bread and special sauce

#### Tell A Story

#### Every story needs the same elements:

- A Compelling Plot
  - In our world, a compelling scientific problem
  - Something you (and the reviewers) are passionate about
- Tension / Conflict
  - In science, the knowledge gaps and the technical obstacles that have prevented solving those knowledge gaps
- Action Solving the Problem
  - Focused aims / objective / tasks the battle plan
  - Technical Approach executing the plan
  - Contingency Plans pitfalls and alternatives
- Resolution
  - How the field will be changed as a result of this research
  - Future directions for building on this research

#### **Know Your Audience**

#### What is the funding agency looking for?

Basic Science – or Translation?

Topics in an RFA?

Single Investigator, or a Team?

What problems do they REALLY care about?

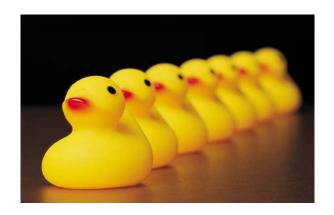
#### **Follow Directions!**

#### Is there an RFP? READ IT!

Is your idea responsive to the call? Point that out, explicitly

If you're not responsive - don't waste your time

When in doubt - talk to Program!



#### Follow the Format - Don't Cheat!

Densely written text will discourage and bore the reader

Complex figures will discourage the reader

Flowcharts really help!

#### Cut to the Chase!

Focus on What is Essential

Show your Logic

Leave the details to later

Keep it SIMPLE!

## The Mechanics – What a Good Proposal Looks Like

- ▶ The Plot
  - State the problem you want to solve
  - The problem should be important (significant)
  - It should open up new ground, not simply flesh out existing knowledge (the dreaded incremental project!)
  - The problem should be solvable with your approach, on time and on budget
- Tension / Conflict
  - Succinctly describe why this problem has not been solved yet
  - Clearly state what you are doing differently that will result in a solution
    - It could be a new way of looking at the problem, or a new technical tool, or a unique team of experts
  - INNOVATION lies in the uniqueness of your approach to the problem

## The Mechanics – What a Good Proposal Looks Like

- Strategic Action Plan
  - State specific aims / objectives / tasks
    - These must be very carefully crafted
    - It must be clear that achieving these aims will solve the problem posed
    - Aims should not be co-dependent, but each should stand alone
    - The flow of information and effort between the aims should be evident
  - Each aim / objective should include a very succinct description of the approach
    - One sentence or clause per aim
    - Subaims are okay, if used wisely
  - Make sure the logical connection between the aims is clear

## The Mechanics – What a Good Proposal Looks Like

#### The Cast

- One sentence demonstrating why you (and your team) are right for the job
- Referenced to objective accomplishments, not subjective opinions
- Highlight what is unique about PNNL

#### Resolution

- What you will know, or not know, at the end of the project
- Brief indication of future directions where you will go next after this project
- IMPACT: how your work will change the field

## The First Page Dissected – How to implement the mechanics

- ► The Plot Colon cancer is a fatal disease if not detected early. Current medical practice in the US is screening colonoscopies for all over age 50, but colonoscopies are expensive and invasive. Screening for occult blood in stool is inexpensive but ineffective, and many cancers are missed. A blood test that could accurately detect colon cancer very early would save lives
- ► Tension Current approaches for measuring proteins in blood are relatively insensitive, and unlikely to detect cancers early enough. Human variability and low signal means many independent patient samples must be measured
- Solution New proteomic technologies developed by my group offer both the sensitivity and throughput needed to identify and validate blood biomarkers for early detection of colon cancer

## The First Page Dissected – How to implement the mechanics

#### ► Action Plan-

- Specific Aim 1: Identification of plasma proteins associated with early stages of colon cancer, using novel mass spectrometric approaches that provide absolute protein abundance measurements down to pg/ml levels. These measurements will be applied to a unique cohort of colon cancer patients available from clinical collaborators
- Specific Aim 2: Bioinformatic analysis of over-represented proteins for enrichment of specific functions using a variety of software tools including KEGG, BIND, and MetaCor
- Specific Aim 3: Selection and Validation of candidate biomarkers
  Candidate biomarkers selected on the basis of functions known
  to be associated with carcinogenesis will be verified by
  orthogonal approaches. The top ten ten verified candidates will
  be assessed in 1000 prospectively collected plasma samples
  from early stage colon cancer patients, using a novel high
  throughput proteomics approach

## The First Page Dissected – How to implement the mechanics

#### ► IMPACT –

The end product will be an affordable accurate blood test for early detection of colon cancer without colonoscopy. Successful demonstration of this approach in colon cancer will enable application to other cancers in need of a early detection biomarkers. Future directions of this research also include the application of a systems biology approach to the large datasets generated in the discovery phase, to provide new insights about the earliest stages of colon cancer.

#### It all fits on one page:

Colon cancer is a fatal disease if not detected early. Current medical practice in the US is screening colonoscopies for all over age 50, but colonoscopies are expensive and invasive. Screening for occult blood in stool is inexpensive but ineffective, and many cancers are missed. A blood test that could accurately detect colon cancer very early would save lives. Current approaches for measuring proteins in blood are relatively insensitive, and unlikely to detect cancers early enough. Human variability and low signal means many independent patient samples must be measured. New proteomic technologies developed by my group offer both the sensitivity and throughput needed to identify and validate blood biomarkers for early detection of colon cancer.

This work will be accomplished through the following specific aims:

Specific Aim 1: Identification of plasma proteins associated with early stages of colon cancer, using novel mass spectrometric approaches that provide absolute protein abundance measurements down to pg/ml levels. These measurements will be applied to a unique cohort of colon cancer patients available from clinical collaborators

Specific Aim 2: Bioinformatic analysis of over-represented proteins for enrichment of specific functions using a variety of software tools including KEGG, BIND, and MetaCor

Specific Aim 3: Selection and Validation of candidate biomarkers Candidate biomarkers selected on the basis of functions known to be associated with carcinogenesis will be verified by orthogonal approaches. The top ten ten verified candidates will be assessed in 1000 prospectively collected plasma samples from early stage colon cancer patients, using a novel high throughput proteomics approach

The end product will be an affordable accurate blood test for early detection of colon cancer without colonoscopy. Successful demonstration of this approach in colon cancer will enable application to other cancers in need of a early detection biomarkers. Future directions of this research also include the application of a systems biology approach to the large datasets generated in the discovery phase, to provide new insights about the earliest stages of colon cancer.

## What is the ONE most important thing you can do?

## GET ANOTHER SET OF EYES



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 Associate Professor
 UT Health Science Center. San Antonio

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- Gina Schatteman, PhD., Integrative Physiology, University of Iowa

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