# **GREAT IDEAS 1-25**

Faculty Development Committee
Scholarship Subcommittee

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# The foundation of your proposal: The Hypothesis

- The hypothesis is the destination of your project. All roads (Aims) should lead to this
  destination.
- A hypothesis should increase understanding of biologic processes, diseases, treatments and/or preventions with a focus on *mechanisms*.
- A good hypothesis should be explanatory, not descriptive:
  - This proposal seeks to test the hypothesis that the capacity of Mycobacterium tuberculosis to inhibit infection-induced apoptosis of macrophages is a major pathway of the bacteria to avoid the host's innate and adaptive immune response.
    - ----NOT-----
  - Understanding the strategies of Escherichia coli to subvert host cells will allow for improved ways of preventing and treating E. coli -related diseases.
- Your proposal should be driven by one or more hypotheses, not by advances in technology (i.e., it should not be a method in search of a problem).
- State your hypothesis in both the specific aims section of the research plan and the abstract / summary.
- Hypothesis doesn't need to be right, just testable!

http://www.ninds.nih.gov/funding/write\_grant\_doc.htm

http://www.tufts.edu/vet/faculty\_research/grant\_writing.html

http://funding.niaid.nih.gov/researchfunding/newsletter/2010/pages/1027.aspx#f01

# GREAT Ideas #2 SPECIFIC AIMS – Your grant in a nut shell.

- The Specific Aims page can make or break your grant and defines everything that follows.
- Get input on this page from colleagues early and often.
- Do not move on to the rest of the grant until the Specific Aims are rock solid.
- Try the attached template!

## Specific Aims should:

- 1. Tell the reader **why** you want to do the work
- 2. Describe what you want to do
- 3. Explain *how* you will do it

# Common problems with specific aims:

- Too ambitious, too much work proposed
- Unfocused aims, unclear goals
- Limited aims and uncertain future directions

http://www.ninds.nih.gov/funding/grantwriting\_mistakes.htm http://morganonscience.com/

# SIGNIFICANCE: Why should anyone else care about your project?

The Significance section is the first section of the NIH's revised Approach section and replaces the former Background and Significance. Emphasize the scope of the problem and how *your* project will fill a gap in the existing knowledge. The NIH has to justify the significance of the funded work to the congress and taxpayers. Provide epidemiological data and/or statistics to help the reviewers make the link!

## Significance section should:

- Make a compelling case for your proposed research project. Why is the topic important? Why are the specific research questions important? How are the researchers qualified to address these?
- Establish significance through a careful review of published data in the field, including your own. Avoid outdated research. Use citations not only as support for specific statements but also to establish familiarity with all of the relevant publications and points of view. Your application may well be reviewed by someone working in your field. If their contributions and point of view are not mentioned, they are not likely to review your application sympathetically.
- Highlight success of your related grants and awareness of potential barriers and alternative approaches.
- Highlight why research findings are important beyond the confines of a specific project i.e., how can the results be applied to further research in this or related areas.
- Clearly state public health implications.

# Common Problems with Significance:

- Not significant nor exciting nor new research
- Lack of compelling rationale
- Incremental and /or low impact research

http://www.ninds.nih.gov/funding/grantwriting\_mistakes.htm

# INNOVATION – What you can do that no one else can.

NIH description of Innovation:

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

http://grants.nih.gov/grants/peer/critiques/rpg.htm

Your challenge is to meet the NIH's request for innovation while still appealing to the study section's tendency to reward low-risk projects.

- Find the *Innovation* in your work. Innovation can include both techniques and concepts. Explain what you can do that others can't and take time to convey the novelty of your work.
- Propose to solve a problem in a new way.
- Emphasize and demonstrate feasibility of your innovative concept / technique / solution.

Here is a quote from the NIAID website on the issue:

"When you look at our sample applications, you see that both the new and experienced investigators are not generally shifting paradigms. They are using new approaches or models, working in new areas, or testing innovative ideas."

http://blog.citizen.apps.gov/NIAIDFunding/2011/01/writing-the-research-strategy/

# Preliminary Data - Make it count!

With the new, shorter NIH grant formats, where to show your preliminary data has become something of a challenge. There is probably not one right way to do this – but here is what the NIAID has to say:

"You can either include this as a subsection of Approach or integrate it into any of the three main sections."

http://funding.niaid.nih.gov/researchfunding/grant/cycle/pages/part05.aspx#a2b

- Include only key *Preliminary Data* that support the Aims and hypothesis.
- 7-8 figures for a 12+1 page grant is a general guideline; 3-4 Figures per Aim.
- Although it is tempting to try and save space, Figures and legends MUST be large enough to be easily read. A guideline would be a font of at least Ariel 9 point in the legend and Ariel 7 points in the figure.

# Keith Yamamoto's Strategy: 'FeedForward'

Rather than feed back, Dr. Yamamoto, chairman of the Advisory Committee to the CSR and as a member of the NIH director's Peer Review Oversight Group, the CSR Panel on Scientific Boundaries for Review, and the Advisory Committee to the NIH Director, recommends that grant writers ask for 'feed forward'. Here's how it works:

- -5. Choose three senior colleagues as your "grant committee"
- -4. Read Criteria for Rating of NIH Grant Applications
- -3. 'Feedforward 1': Discuss (1.5 hr) goals, aims, ideas with committee
- -2. Draft one page with 3-5 Specific Aims
- -1. 'Feedforward 2': Discuss (1.5 hr) with committee

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- 1. Finalize Aims. Draft Abstract, Approach and Innovation
- 2. Draft Significance
- 3. Re-read Criteria for Rating of NIH Grant Applications
- 4. Seek feedback from committee

career.ucsf.edu/pass/Yamamoto-NIHslides-2010final.ppt

# GREAT Ideas #7 EXPERIMENTAL APPROACH

The single sub score that best correlates with overall impact score is the APPROACH. A fundable project will need a score of 1 or 2 for APPROACH.

- Emphasize *mechanism:* A good grant application asks questions about biological mechanisms.
- A picture/diagram to explain your *Experimental Approach* is worth a thousand words!
- Feasibility is key. Make sure you convince reviewers that you can do what you propose.
   Demonstrate feasibility though preliminary data, citing your publications, and/or enlisting a knowledgeable collaborator (or an expert consultant) with a published track record in that area.
- Discuss anticipated outcomes, even those that do not support your hypothesis.
- Anticipate pitfalls and discuss alternatives.
- Provide a time line for each Aim.

#### Common problems with experimental approach:

- Too much unnecessary experimental detail
- Not enough detail on approaches, especially untested ones
- Not enough preliminary data to establish feasibility
- Feasibility of each aim not shown
- Little or no expertise with approach
- Lack of appropriate controls
- Not directly testing hypothesis
- Correlative or descriptive data
- Experiments not directed towards mechanisms
- No discussion of alternative models or hypotheses
- No discussion of potential pitfalls
- No discussion of interpretation of data

http://www.ninds.nih.gov/funding/grantwriting\_mistakes.htm http://www.ninds.nih.gov/funding/write\_grant\_doc.htm

# Details, details, details....

**Everything counts!** With the new scoring system fundable grants and triaged grants can be clustered just a few points apart. Neatness counts! Spelling counts! Grammar counts! Attention to detail counts! Letters of Collaboration count! Budget justifications (if applicable) count! Biosketches counts!

Keep an eye out for these pitfalls:

# **Problems with investigator:**

- No demonstration of expertise or publications in approaches
- Low productivity, few recent papers
- No collaborators recruited or no letters from collaborators

#### **Problems with environment:**

- Little demonstration of institutional support
- Little or no start up package or necessary equipment

# Your revised grant: A1 Strategy

- When preparing an A1 first address the points highlighted in the Summary of
   Discussion, if available. Then address individual reviewer concerns in the remaining
   space. It is legitimate to use the grant body to add to or complete this process if needed
   in the appropriate sections.
- Don't rush a resubmission. Sit out a round and skip a deadline if needed to return a better grant.
- Don't make your reviewers dig for new information in a revised grant. Indicate changes clearly and help them to help you!
- Even if you disagree with a reviewers point be diplomatic. Consider one of the following openings:
  - We understand what the reviewer is saying, but respectfully disagree because....
  - The reviewer raises an excellent point.....
- Thank them for their time.
- Know when a grant can be revised sufficiently to justify a resubmission and when it can't. If all reviewers are on the same page and you can address the concerns comprehensively you have a good chance of succeeding. If the reviewers have conceptual issues you may be better off constructing a new application.

# GREAT Idea #10 What Does the NIH Look For In a Grant?

#### **Projects of High Scientific Caliber**

NIH looks for grant proposals of high scientific caliber that are relevant to public health needs and are within NIH Institute and Center (IC) priorities. ICs highlight their research priorities on their individual websites. Applicants are urged to contact the appropriate Institute or Center staff to discuss the relevancy and/or focus of their proposed research before submitting an application.

#### **NIH-Requested Research**

NIH Institutes and Centers regularly identify specific research areas and program priorities to carry out their scientific missions. To encourage and stimulate research and the submission of research applications in these areas, many ICs will issue <u>funding opportunity announcements (FOAs)</u> in the form of <u>program announcements (PAs)</u> and <u>requests for applications (RFAs)</u>. These FOAs may be issued to support research in an understudied area of science, to take advantage of current scientific opportunities, to address a high scientific program priority, or to meet additional needs in research training and infrastructure. To find an FOA in your scientific field, search the <u>NIH Guide for Grants and Contracts</u> which includes all funding opportunities offered by NIH, or <u>Grants.gov</u> to search across all Federal agencies.

#### **Unsolicited Research**

NIH supports "unsolicited" research and training applications that do not fall within the scope of NIH-requested targeted announcements. These applications originate from your research idea or training need, yet also address the scientific mission of the NIH and one or more of its ICs. These "unsolicited" applications should be submitted through "parent announcements (PAs)", which are funding opportunity announcements that span the breadth of the NIH mission.

http://grants.nih.gov/grants/grant\_basics.htm

## What are the new NIH Peer Review Criteria?

#### Straight from the horse's mouth:

The goals of NIH-supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will comment on each of the following criteria to evaluate the likelihood that the proposed research will have a substantial impact on the pursuit of one or more of these goals. The overall score is assigned based on the reviews for each of these criteria. Reviewers are instructed to keep the five review criteria in mind; however, the final priority score they assign is more likely to reflect a judgment of overall merit.

**Significance.** Does the project address an important problem or a 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?

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

**Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of

minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

**Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

http://grants.nih.gov/grants/writing\_application.htm

# Are there any Advantages for New or Early Stage Investigators?

## YES!!

- Determine whether you qualify as a new investigator based on the NIH definition of new investigator.
- NIH offers funding opportunities tailored to new investigators, such as the NIH Director's New Innovator Award.
- There is even a New Investigators Program Web page.
- It is to your advantage to identify yourself as a new investigator because reviewers are instructed to give special consideration to new investigators. Reviewers will give greater consideration to the proposed approach, rather than the track record. First-time applicants may have less preliminary data and fewer publications than more seasoned investigators, and NIH reviewers understand this. Reviewers instead place more emphasis on how the investigator has demonstrated that he or she is truly independent of any former mentors, whether he or she has some of his or her own resources and institutional support, and whether he or she is able to independently lead the research.
- Many institutes fund New Investigators up to 5 points above the payline. Check out
  the individual Institutes and Centers for more info:
  http://grants.nih.gov/grants/new\_investigators/index.htm

http://grants.nih.gov/grants/writing\_application.htm

# GREAT Idea #13 ARE YOU A NEW INVESTIGATOR?

## **Definition of New Investigator**

In general, a Program Director/Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial NIH independent research award. Specifically, a PD/PI is identified as a New Investigator if he/she has **not** previously competed successfully for an NIH-supported research project **other than** the following early stage or small research grants or for the indicated training, infrastructure, and career awards:

- Pathway to Independence Award-Research Phase (R00)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Research Education Grants (R25, R90, RL9, RL5)
- Clinical Trial Planning Grant (R34)
- Dissertation Award (R36)
- Small Business Technology Transfer Grant-Phase I (R41)
- Small Business Innovation Research Grant-Phase I (R43)
- Shannon Award (R55)
- NIH High Priority, Short-Term Project Award (R56)
- Competitive Research Pilot Projects (SC2, SC3)
- Resource Access Award (X01)

Additionally, the PD/PI is not excluded from consideration as a "New Investigator" if he/she hasbeen the PD/PI of received an award from any of the following classes of awards:

#### **Training-Related and Mentored Career Awards**

- All Fellowships (F awards)
- All individual and institutional career awards (K awards)
- Loan repayment contracts (L30, L32, L40, L50, L60)
- All training grants (T32, T34, T35, T90, D43)

#### Instrumentation, Construction, Education, Health Disparity Endowment Grants, or Meeting Awards

- G07, G08, G11, G13, G20
- R13
- S10, S15, S21, S22

# Think like a Reviewer

- A reviewer must often read 10 to 15 applications in great detail and form an opinion about each of them. Your application has a better chance at being successful if it is easy to read and follows the format. Make a good impression by submitting a clear, well-written, properly organized application. Include "white space" and proof read!
- Get organized. The instructions require that materials be organized in a particular format.
  Reviewers are accustomed to finding information in specific sections of the application.
  Organize your application to effortlessly guide reviewers through it. This creates an efficient evaluation process and saves reviewers from hunting for required information. Explicitly address each of the NIH's 5 peer review criteria (Significance, innovation, approach, investigator, and environment).
- Know your reviewers; do literature searches of committee members if lists are public. Make sure their work is cited where appropriate.

# Organization, organization!

- Start with an outline following the suggested organization of the application.
- Be complete and include all pertinent information.
- Be organized and logical. The thought process of the application should be easy to follow.
   The parts of the application should fit together. Use sub-headings, short paragraphs, and other techniques to make the application as easy to navigate as possible. Be specific and informative, and avoid redundancies.
- Use diagrams, figures and tables, and include appropriate legends, to assist the reviewers
  to understand complex information. These should complement the text and be appropriately
  inserted. Make sure the figures and labels are readable in the size they will appear in the
  application.
- Use bullets and numbered lists for effective organization. Indents and bold print add readability. Bolding highlights key concepts and allows reviewers to scan the pages and retrieve information quickly. Do not use headers or footers.

# Remember your High School English Teacher!

- Write one sentence summarizing the topic of each main section. Do the same for each main point in the outline.
- Make one point in each paragraph. This is key for readability. Keep sentences to 20 words or less. Write simple, clear sentences. Try these substitutions:

lf

At the present time... **Now** 

Due to the fact that... Because

It may be that... Perhaps

Prior to the start of... Before

On two separate occasions... **Twice** 

• Spell out all acronyms on first reference.

In the event that...

 Use a clear and concise writing style so that a non-expert may understand the proposed research. Make your points as directly as possible. Use basic English, avoiding jargon or excessive language. Be consistent with terms, references and writing style. Try using the shorter of the following words:

Approximately
Commence
Begin
Finalize
Finish
Prioritize
Rank
Terminate
Utilize
Use

- Watch your syntax!
  - "After standing in boiling water, we examined the flask."
  - "Having completed the study, the bacteria were of no further interest."

http://grants.nih.gov/grants/writing\_application.htm

# Persuasive writing: Active not passive voice

The active voice helps your writing to be concise, punchy and easy to read, and is achieved when the subject performs the action expressed by a verb (it's also *shorter!*).

# Examples:

"We will develop an experiment, " not "An experiment will be developed"

"The new drug decreased heart rate" **not** " The new drug caused a decrease in heart rate"

The warning signs of passive sentences are forms of **be**, such as **am**, **is**, **was**, **were**, **are**, or **been**, and frequently when '**by**' is used to link to the subject after the verb. Circle these words and try to substitute them with stronger verbs.

## Examples of strong verbs:

Make an adjustmentAdjustMake a judgmentJudgeMake a decisionDecide

Perform an investigation Investigate

Make a referral Refer

Reach a conclusion Conclude

For more ideas, refer to the attached list of action verbs

http://copywriterscrucible.com/persuasive-writing-7-editing-your-writing/

# Put on your accountant hat.....Budget

- Before you start writing the application, think about the budget and how it is related to your research plan. Remember that everything in the budget must be justified by the work that you have proposed to do.
- Create a budget wish list by reviewing your summary and listing anything and everything
  that is going to cost money, i.e. people's salary and fringe benefits, supplies, travel,
  communication, participant incentives, etc.
- Formulate a realistic budget. Don't propose more work than can be reasonably done during
  the proposed project period. Make sure that the personnel have appropriate scientific
  expertise and training. Make sure that the budget is reasonable and well-justified.

# I'm a salesman?!?

#### From the NIH:

Capture the reviewers' attention by making the case for why NIH should fund your research. Tell reviewers **why** testing your hypothesis is worth NIH's money, **why** you are the person to do it, and **how** your institution can give you the support you'll need to get it done. Be persuasive.

## http://grants.nih.gov/grants/writing application.htm

- Directly address the relevance of your proposal to the goal/aim/request of the funding agency. If you are responding to an NIH RFA, emphasize how your project addresses the request. If you are writing to the VA or the AHA, explicitly state how your project will improve veterans' health and or heart disease.
- Don't over-sell. Your project must be relevant to the goal or disease focus of the
  organization but your ideas will probably not lead to the eradication of heart disease or a
  cure for cancer. The benefit to the funding agency should be exciting but deliverable.

# Communicate with the funding agency

At the end of the day, a grant is a business transaction. And in business, relationships are key. So (unless forbidden by the agency) communicate with your program officer!

- Call the Program Officer (PO) prior to grant submission, especially for an RFA. In addition,
   Contact a program officer to do the following:
  - o Discuss whether your proposed topic would fit into his or her program.
  - Find out about the funding status of your application after receiving your summary statement. Check your <u>eRA Commons</u> account for application information.
  - Get information on scientific and programmatic matters concerning your grant.
  - Ask questions about NIH policies, including:
    - <u>Data Sharing</u>—read our <u>Data Sharing for Grants: Final Research Data SOP.</u>
    - Model Organism Sharing—read our Sharing Model Organisms SOP.
    - Public Access—get an overview in our <u>Public Access of Publications</u> SOP.
  - Obtain details on managing your grant. Read <u>Part 11a. Managing Your Grant</u> in the <u>NIH Grant Cycle: Application to Renewal</u>.
  - Discuss prior approval requirements. See the <u>Prior Approvals for Post-Award Grant</u> Actions SOP.
  - Discuss issues that may affect progress on your research aims.
     http://funding.niaid.nih.gov/researchfunding/sop/pages/programofficer.aspx
- Call the Scientific Review Officer (SRO) after study section review for additional insight into your grant's outcome. Names and contact information can be found in the program announcement for your grants.
- Include a cover letter with your grant application.
  - From NIH: "Although though not a requirement for assignment purposes, a cover letter
    can help the Division of Receipt and Referral in the Center for Scientific Review assign
    your application for initial peer review and to an IC for possible funding."

# Try these formatting tips

- 1. **Don't justify** the right hand margin. Uneven right hand margins make it easier for the reader. Only justify right margins if using columns or if it's required.
- 2. **Single space** unless the funding agency tells you otherwise.
- 3. Use *headings* as required by the application, but add your own subheadings to improve readability.
- 4. Include "*white space*" on your proposal. It's restful to the eye and signals a transition in information.
- 5. Use an **Arial**, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies; NIH requires Arial 11pt.)
- Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Use standard paper size (8 ½" x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

http://www.vir-sys.com/founded/tips.htm

# **The Drop Dead Experiment**

Know what the *Drop-Dead Experiment* is for your project. This is *the* experiment that will provide the data that could potentially disprove your hypothesis. Identify this experiment in your planning stages. Make you sure you have done it, that the result supports your hypothesis (if not, change your hypothesis), and highlight this key experiment in your preliminary data.

# Don't fall in love with your hypothesis

A hypothesis is a testable answer to a question. *But it doesn't have to be true!* A good approach will take into consideration all likely outcomes – even those that disprove the hypothesis. Include alternative ideas / approaches to address this possibility.

Remember – your hypothesis doesn't have to be *right*. Just testable!

# The Four draft strategy:

Treat draft writing as a meeting or consultation and schedule it. Plan to have four drafts of your proposal:

**First draft** is for free writing, with no worries about grammar or style. Have several people read this draft. Prepare specific questions for them to answer regarding the proposal.

**Second draft** shapes feedback into the proposal's content, so it moves toward the final document. Have one or two people read it again. Also, ask for a "fair witness" reading. A fair witness is someone who doesn't know your program but whose judgment you trust.

**Third draft** is for serious editing on punctuation, word usage, active vs passive voice, and flow. Apply the "English teacher test." Again, this person should be someone who has not yet read the proposal. Fresh eyes will see mistakes missed by the writer and other reviewers.

**Fourth draft** will probably be the last draft. If you are able to, wait on it a few days and then read it. Read it aloud. If it doesn't *sound* good, if might not *read* well either.

http://www.vir-sys.com/founded/tips.htm

# **Top 10 Fatal Grant Flaws**

10. Waiting until the last minute.	Grant lacks polish and contains avoidable errors.

9. Wrong funding mechanism.	Feasibility is questioned and study appears premature.
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8. Human Subjects concerns. Implies that the PI is unprepared and/or unethical.

7. Weak statistics/study power. Questions feasibility of the project and PI's experience.

**6.** Lack of a back-up plan. Suggests the project is a "house of cards".

**5. Gaps in expertise.** Project appears overly ambitious with poor feasibility.

**4. Poor organization.** Reviewers get lost and miss important aspects.

3. Missing / problematic hypothesis

Project appears "descriptive"; study design "lacks focus".

2. Lack of Significance / Innovation

Project will fail to generate the necessary enthusiasm.

1. Overly Ambitious

Questions the feasibility and budget of the project.

Adapted from: Strathdee and Patterson gph.ucsd.edu/resources/student/10flaws.ppt