Understanding the NIH Peer Review Process

Presented by
Jo Anne Goodnight
Independent Consultant
(Former NIH SBIR/STTR Program Manager)

Joanne.goodnight@gmail.com

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Grant Writing for Success

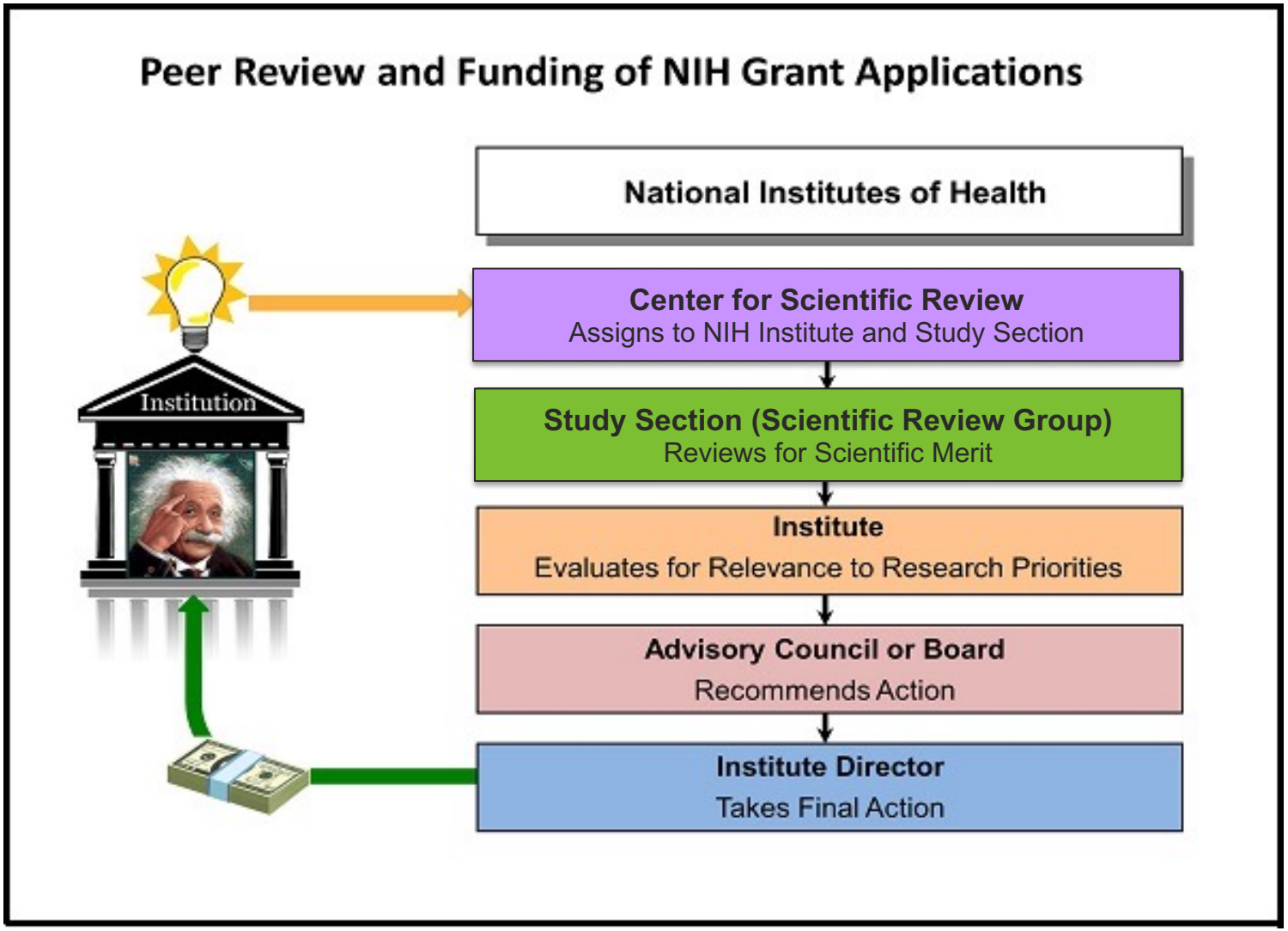
My Background

- 25+ years in the Federal Government
  - NIH: SBIR/STTR Program Manager; Researcher
    - Office of the Director
    - National Cancer Institute
  - FDA
  - USDA
  - Interagency policies/initiatives (DOD, NSF, DOE, NASA, DHS, etc.)
- 10+ years in non-profit and for-profit environments
  - Jackson Laboratory, Director of Sponsored Research
  - Small TX biotech company, VP Research
  - Small FL-based consulting company, Program Manager
- Scientific Background
  - Microbiology and immunology
  - Cancer genetics

Today's Objectives:

- Understanding the NIH Peer Review Process

The NIH Peer Review Process
30,000 Foot Level



The NIH Peer Review Process

Scientific Review Group (SRG)

- Provides independent outside review
- Makes recommendations – not funding decisions!
  - Scientific and technical merit
  - Budget and project duration
  - Protection of human subjects, vertebrate animals, biohazards
  - Resource Sharing Plans
  - Other administrative factors

1st level

~3 months after submission

Output: Impact Score and Summary Statement

3 - 6 months

Advisory Council

- Assess quality of SRG process
- Advise on new concepts (future FOAs)
- Evaluate program priorities and relevance
- Offer recommendations to Institute Staff
- Advise on policy

2nd level

Output: Funding Recommendations

1 - 3 months

Institute Director

- Makes final decision based on:
  - Council input
  - Programmatic priorities
  - PO recommendations

Output: Funding decision

The NIH Peer Review Process

Scientific Review Group Assignments

- **For each application:**
  - ≥ Three qualified reviewers are assigned
  - Assignments made by SRO based on:
    - Scientific content of application
    - Expertise of the reviewer
    - Suggestions from the PI on types of expertise – ***no names!***
    - Suggestions from Program staff
    - Suggestions from SRG members
    - Managing conflicts of interest
    - Balancing workload

Assignments are confidential!

The NIH Peer Review Process

Evaluation of Grant Applications

- Overall Impact
- Scored Review Criteria
- Additional Review Criteria
- Additional Review Considerations

SRG rosters posted 30 days prior to meeting:

https://public.era.nih.gov/pubroster/rosterIndex.era

https://public.csr.nih.gov/StudySections/SmallBusinessAndTechnologyTransfer

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Overall Impact [Score]: ***Likelihood of project to have sustained, powerful influence on the research field(s) involved.***

Based on:

- Five individually scored criteria
  - **Significance**
  - **Innovation**
  - **Approach**
  - **Investigator(s)**
  - **Environment**
- Additional review criteria

See "Review Criteria at a Glance"
(http://grants.nih.gov/grants/peer/reviewer_guidelines.htm)

Research Strategy Section

- Your Research Strategy is **the** major part of your Research Plan (the other part is the Specific Aims.)
- The nuts and bolts of your application
  - Rationale for your research and the experiments you will do to accomplish each aim.
- Three main sections
  - Significance
  - Innovation
  - Approach

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Scored Review Criteria

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 completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Significance Section

- Significance section should give the most details.
- Don't skimp—the farther removed your reviewers are from your field, the more information you'll need to provide on basic biology, importance of the area, research opportunities, and new findings.
- Describe significance in the context of 1) the state of your field, 2) your long-term research plans, and 3) any preliminary data you may have.
- Make a case for the importance of the research to improving human health as well as to the scientific field.
- Make the scientific premise explicitly clear.

Significance Section – Checkpoint

- ❑ I describe the importance of my technology to the field (especially if my reviewers are not in it).
- ❑ I also point out the project's significance throughout the application.
- ❑ The application shows that I am aware of opportunities, gaps, roadblocks, and research underway in my field.
- ❑ I state how my research will advance my field, highlighting knowledge gaps and showing how my project fills one or more of them.
- ❑ I scan the review committee roster from prior cycles and cite some of the reviewers' work.

The NIH Peer Review Process

Scored Review Criteria

Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms e.g., by utilizing novel approaches or methodologies, instrumentation, or interventions?
- Are the 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 approaches or methodologies, instrumentation, or interventions proposed?

Innovation Section

- Describe how your proposed research is new and unique, e.g., explores new scientific avenues, has a novel technology that will create new knowledge.
- Include a competitive landscape chart

LEGEND ■ YES □ NO	Competitor 1	Competitor 2	Your Product
Test			
in vitro	□	□	■
in vivo	□	■	□
Detection			
Direct	□	□	■
Indirect	■	■	□
Time to Result			
<1 hour	□	□	■
1-24 hours	□	■	□
48-72 hours	■	□	□
Result Interpretation			
Objective	■	□	■
Subjective	□	■	□
Diagnostic Setting			
Peripheral Laboratory/POC Setting	□	□	■
Clinical Lab	■	■	□
Patient Visits			
One	□	□	■
Two or more	■	■	□
Training			
Minimal; requires no highly skilled personnel or special equipment	□	□	■
Extensive; requires technical personnel and/or specialized equipment	■	■	□

Innovation Section – Checkpoint

- ❑ I show how my proposed research is new and unique, e.g., explores new scientific avenues, will create new knowledge.
- ❑ I explain how my project's research can refine, improve, or propose a new application of an existing concept or method.
- ❑ I explain how my project's research can shift a current paradigm (e.g., data to support the innovative approach.)

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Scored Review Criteria

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 project is in early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- If project involves clinical research, are plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, and 3) the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

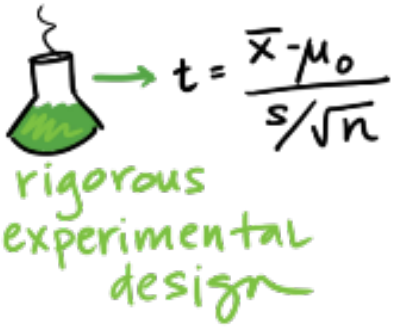
Approach Section

Outline, organize and write to the peer review criteria

- Organize the Approach around your Specific Aims
- Detail a few sets of experiments to address each aim.
- Include preliminary data or cite data from the literature.
- Expect reviewers to scrutinize your approach:
  - They will want to know <u>what</u> you plan to do and <u>how</u> you plan to do it.
- Cite a publication that shows you can carry out the method.
  - Provide details if you don't have a proven record using the method—and state explicitly why you think you will succeed.

Scientific Rigor

- Succinctly state what is planned to ensure scientific rigor.
- Include numbers, specific details, etc.
  - sample numbers
  - blinding & randomization
  - study power
  - statistical analysis



Approach Section – Structuring Tips

- Enter a bold header for each Specific Aim.
  - Under each aim, describe the first set of experiments.
  - Outline the branching of next steps.
- Discuss potential pitfalls and alternative strategies

- Include a project timeline or program schedule.

PROGRAM TIMELINE	Yr1: Q1	Yr1: Q2	Yr1: Q3	Yr1: Q4	Yr2: Q1	Yr2: Q2	Yr2: Q3	Yr2: Q4
Aim 1: Assay Development								
1.1 p24 mAb selection / optimization	■	■	■	■				
1.2 HIV-1 and -2 antigen selection	■	■	■	■				
1.3 Viral disruption assay			■	■	■			
Aim 2: Cartridge Integration								
2.1 Fluidic channel geometry	■	■	■					
2.2 Sample loading / inlet port design		■	■	■				
2.3 Internal QC			■	■	■	■	■	
2.4 On-board reagents	■	■	■	■	■	■	■	
Aim 3: Assay Validation								
3.1 HIV positive panel			■	■	■			
3.2 HIV negative panel				■	■			
3.3 Interfering substance						■		
Aim 4: Pre-Market Field Evaluation								
4.1 Study plan			■	■				
4.2 Usability testing				■	■	■	■	
4.3 Prospective study (100 donors)					■	■	■	■

Approach Section – Checkpoint

- ❑ I include enough background and preliminary data (or literature citations) to give reviewers the context and significance of my plans.
- ❑ Each of my Specific Aims results in a set of experiments.
- ❑ I show alternative experiments and approaches in case I get negative or surprising results.
- ❑ My experiments can yield meaningful data to support my rationale.
- ❑ I include enough detail to convince reviewers I understand and methods.
- ❑ I explicitly state my team's resources and expertise.
- ❑ I describe the results I anticipate and their implications.
- ❑ I omit all information not needed to state my case.
- ❑ I keep track of and explain **who** will do what, **what** they will do, **when** and **where** they will do it, **how long** it will take, and **how much money** it will cost.
- ❑ My timeline shows when I expect to complete my aims.

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Scored Review Criteria

Investigator(s)

- Are the PD/PIs, collaborators, and other researchers well suited to the project?
- Do investigators have appropriate experience and training?
- Do investigators demonstrate an ongoing record of accomplishments that have advanced their field(s)?
- Multi-PD/PI: Do PIs have complementary and integrated expertise; are leadership approach, governance and organizational structure appropriate for the project?

Biosketch is KEY!

Your Biographical Sketch

- Provides reviewers with a summary of key personnel's academic and professional backgrounds, achievements, and major scientific accomplishments.
- **Always tailor your personal statement to the grant application you are writing!**
- Maximum five pages.

The NIH Peer Review Process

Scored Review Criteria

Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are 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, or collaborative arrangements?

Facilities/Resources and Equipment are KEY!

Facilities and Other Resources

- Describe the resources you need and those that are available to you. Work with your company leadership to identify the resources and level of support your company can provide and external resources you can leverage.
- If you have collaborators, indicate what they can offer.
- Convey how the scientific environment in which you will conduct your research contributes to the probability of success (e.g., company support, physical resources, and intellectual rapport).
- Peer reviewers will consider facilities as part of their evaluation of “Environment”- provide sufficient detail.

Equipment

- List major items of equipment already available for your project.
- If you need expensive equipment, consider leasing it (especially in Phase I).
- If you need to purchase equipment, provide a strong, detailed justification explaining why it is essential for your specific project.
- Peer reviewers will consider equipment as part of their evaluation of “Environment”- provide sufficient detail.

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Additional Review Criteria

As applicable for the project proposed

No separate scores for these items.

Considered in overall impact/priority score

- *FOA-specific criteria*
- *Protections for Human Subjects*
- *Inclusion of Women, Minorities, and Children*
- *Vertebrate Animals*
- *Resubmission Applications*
- *Renewal Applications*
- *Revision Applications*
- *Biohazards*

Common Application Problems

Problems with Significance

- Scientific premise is weak or not even stated
- Neither significant nor exciting new research (i.e., won't advance science)
- Lack of compelling rationale
- Incremental science; low impact research

Problems with Innovation

- Not clearly addressed in application
- Not innovative (i.e., new, improvement over existing technology).

Problems with Specific Aims:

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

Common Application Problems (cont.)

Problems with Experimental Approach:

- Too much unnecessary experimental detail
- Not enough detail on approaches
- Not enough preliminary data (or literature research) to show likelihood of establishing feasibility
- Little or no expertise with approach
- Lack of appropriate controls
- Correlative or descriptive data
- No discussion of potential pitfalls
- No discussion of interpretation of data

Common Application Problems (cont.)

Problems with Investigator/Team:

- No demonstration of expertise or publications in approaches
- Low productivity, few recent papers
- No collaborators recruited or no letters from collaborators
- Team has not worked together in the past

Problems with Environment:

- Facilities/Other resources not well described
- Necessary equipment is not available

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NIH Scoring System

- **Numerical scores**
  - 9-point scale
  - 1 (exceptional) to 9 (poor)
- **Preliminary scores** (before the SRG meeting)
  - Entered by assigned reviewers in secure website
  - Made available to other SRG members
- **Overall Impact scores**
  - Voted by all eligible (w/o COI) reviewers
  - Voted by private ballot at the meeting
- **Scored Review Criteria**
  - Given by assigned reviewers as part of their critiques
  - Generally not discussed at the meeting

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Score Descriptors

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	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
Low	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

Guidelines: Peer Review Scoring System and Procedure

The NIH Peer Review Process

Streamlining: Triage Process

- Allows discussion of most meritorious applications
- Non-competitive applications are not discussed
- Requires concurrence of the entire review panel
- Summary statement:
  - “Score” designated ** or Not Discussed (ND)
  - No “Resume and Summary of Discussion”
  - Contains reviewer critiques and criterion scores

My Application has Been Reviewed…

Now What?????

Post Review Steps

- **Check eRA Commons** (https://era.nih.gov/)
  - Impact/Priority Score posted 3 days after SRG meeting
  - Summary statement available 4 – 8 weeks later
    - Confidential document
    - Available to:
      - PD/PIs
      - NIH Program Officials
      - Advisory Council members

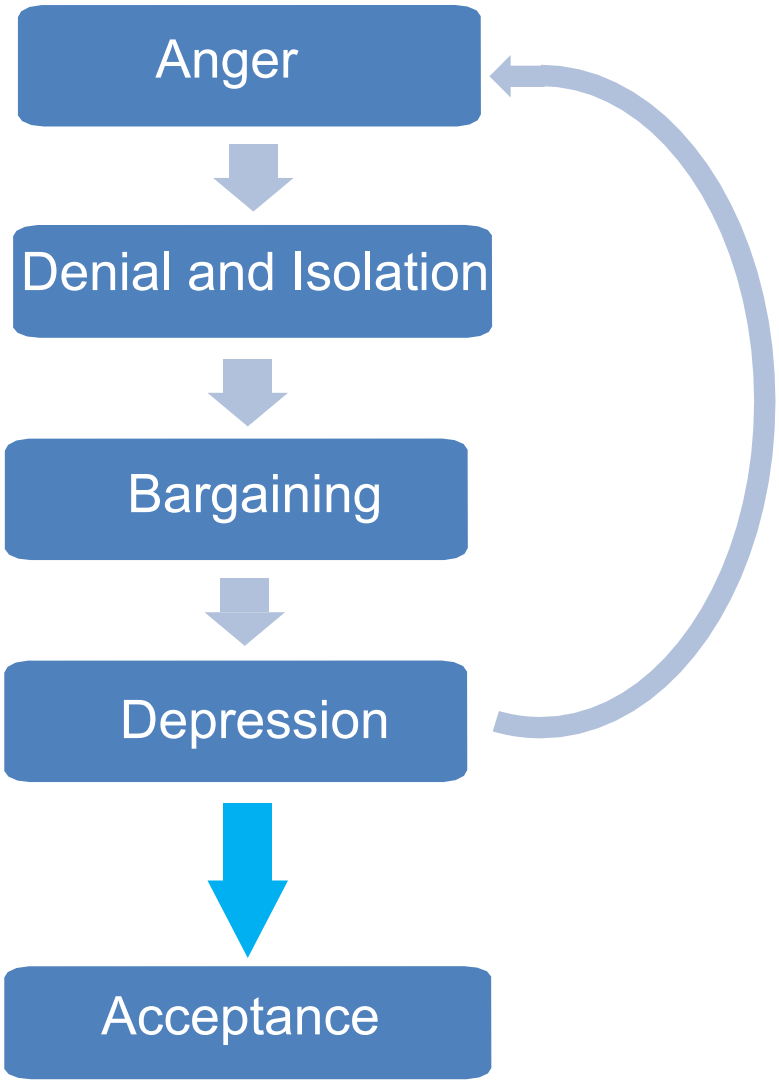
Wait until you have a Summary Statement before contacting your Program Officer

Post Review Steps

Understanding Your Score

- **Impact Score:** Range from 10 to 99 (whole numbers).
  - Smaller is better (e.g., 10 is better than 35).
- **Score with Percentile:** Relative rank of your application compared with others reviewed in your study section at the last three meetings.
- **Score with No Percentile:** Only raw score is given (e.g., SBIR/STTR, SEPs, RFA)
- **Unscored (**):** Scientific merit ranked in lower 50%
- **Not Recommended for Further Consideration**
  - Indication of serious concerns (e.g., unethical).
  - Not eligible for funding

In cases of an unfavorable outcome…
Steps of Bereavement



Post-Review Steps

- Schedule a call with your Program Official -- *not* the Scientific Review Officer.
- Questions you should you ask:
  - What's my likelihood of funding?
  - Consider resubmitting?
  - Timing for funding consideration?
  - Usefulness of brief summary of major issues?

Post-Review Steps

Likelihood of Funding… Depends on many factors

- Beginning of the fiscal year: Wait game - funding is limited and no budget yet.
- Application missed the payline: May be funded later in the fiscal year.
- Institutes may have funding reserves for high programmatic priority areas or special needs.

Stay in touch with your Program Officer!

Post-Review Steps

What if you *are* being considered for funding?

- Chill the champagne!
- Resolve any concerns noted on SS
- Complete Just-In-Time requirements

Post-Review Steps

What if you're *not* selected for award?

- Assess concerns raised by peer reviewers
- Discuss options with colleagues
- Prepare to re-apply, if applicable
- Reconnect with your Program Official

Take-Aways

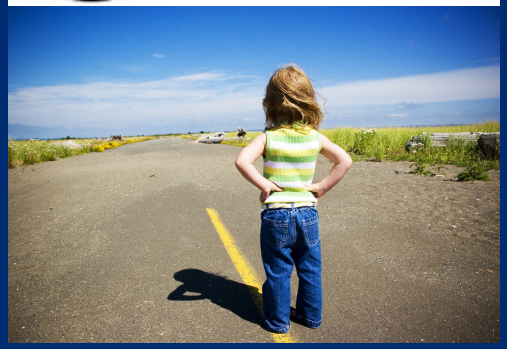
Stay Informed

- Identify appropriate funding opportunities
- Write to the review criteria
- Understand agency missions, programs and priorities

Make Plan: Grants Positioning Strategy

- Plan ahead so you are well-positioned to apply
- Contact agency program staff early
- Read FOA carefully … assess fit… follow instructions
- Know your reviewer audience
- Plan for deadlines and resubmission options

I'm happy to help!



Thank You!

Questions?