The *Art* of Grant Reviewing

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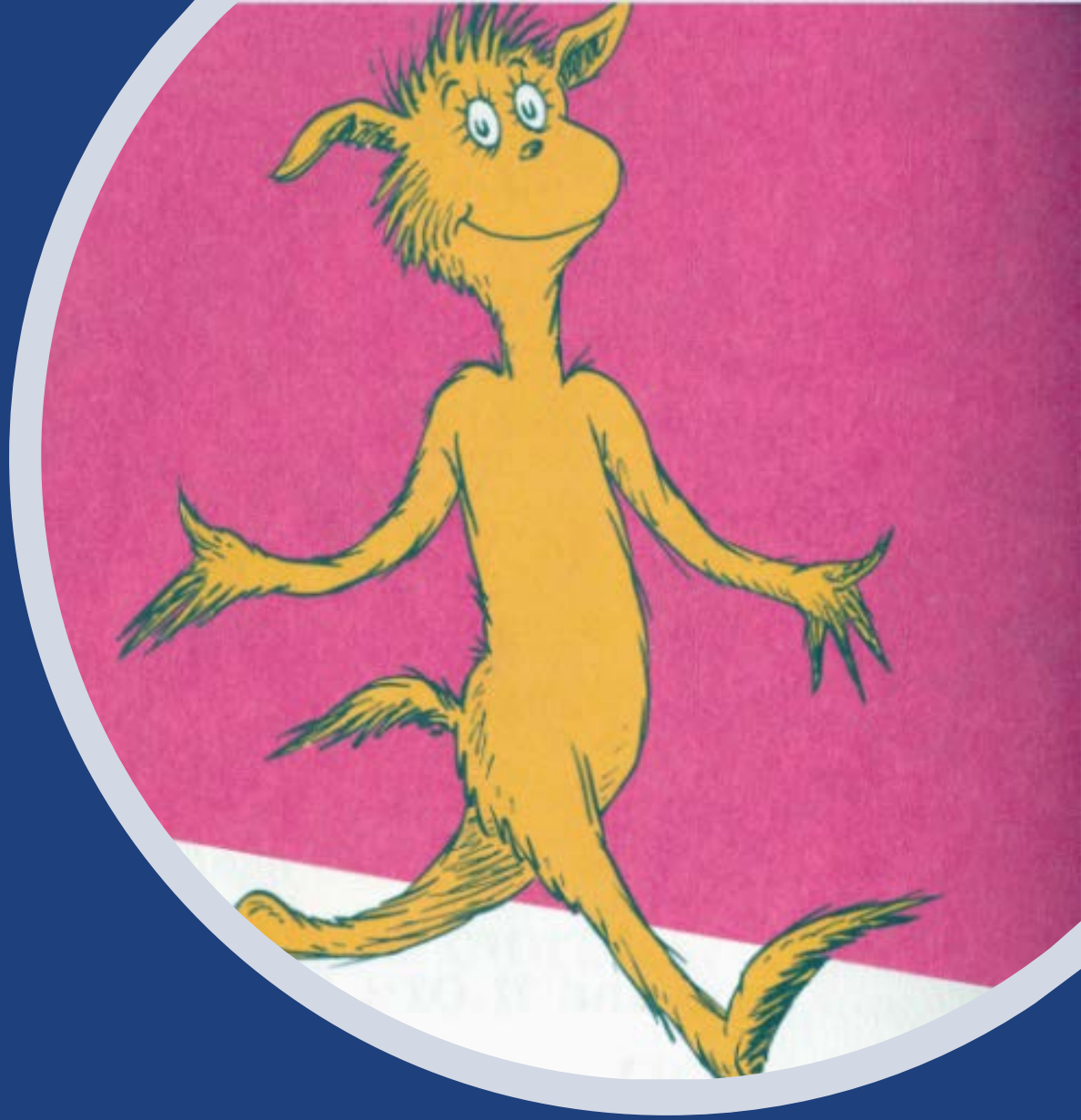
INTRODUCTION

GOAL: Evaluate the scientific merit of proposals in a fair, independent, expert, and unbiased manner

Prepare NIDUS Boot Camp for mock NIH study section process



Materials you have received

- Bootcamp Pilot Grant review assignments
- Proposal review form
- Guide to conducting NIH-style grant reviews
- Sample grant review
- Annals grant writing article–with checklist

An Evidence-Based Guide to Writing Grant Proposals for Clinical Research

Sharon K. Inouye, MD, MPH, and David A. Fiellin, MD

The competition for funds to conduct clinical research is intense, and only a minority of grant proposals receive funding. In particular, funding for patient-oriented research lags behind that allocated for basic science research. Grant writing is a skill of fundamental importance to the clinical researcher, and conducting high-quality clinical research requires funds received through successful grant proposals. This article provides recommendations for the grant-writing process for clinical researchers. On the basis of observations from a National Institutes of Health study section, we describe types and sources of grant funds, provide key recommendations regarding the process of grant writing, and highlight the sections of grants that are frequently scrutinized and critiqued. We also provide specific recommendations to help grant writers improve the quality of areas commonly cited as deficient. Application of this systematic approach will make the task more manageable for anyone who writes grants.

Ann Intern Med. 2005;142:274-282. www.annals.org
For author affiliations, see end of text

High-quality clinical research is essential to understanding disease and improving health care. Each research proposal should provide the potential to add to the existing body of knowledge, to advance understanding, and to alleviate human disease and suffering. However, converting the proposal into reality requires grant funding. In this era of budget cuts and deficits, obtaining peer-reviewed research funds has become ever more competitive. The overall rate of funding of new R01 applications by the National

and comments on grant applications during peer review, and provides recommendations based on this evidence. While some principles may apply to basic science grants, this article is primarily intended for clinical researchers carrying out patient-oriented research. This article is not intended to provide instruction on conducting clinical research. More detailed information on conducting clinical research (5–8) is available elsewhere.

BACKGROUND

Reviewing grants is one of the best ways to learn how to write a grant well

- See how a strong grant shines
- Learn important pitfalls to avoid
- Master how to communicate well across disciplines

Just like when you watch a Ted talk!

BACKGROUND

Our session will also demonstrate how to participate in an NIH-style study section

- Learn how to be a valuable and constructive grant reviewer
- See examples of strengths and weaknesses
- Understand NIH scoring criteria

INITIAL APPROACH

READ THROUGH

Read through first time for “gestalt” and overview: Get a strong sense of the aims and approach

READ THROUGH

Read through again for a more detailed reading, write marginal notes and keep track of major and minor problems identified and strengths which you will use in your writing of the review

ORGANIZE

Organize your thoughts, develop an outline to address the NIH review criteria and WRITE

WRITING YOUR REVIEW

- **Evaluate appropriateness of the approach** (study design, sample, data collection, outcome, statistical analysis, sample size, feasibility)
- **Look at Annals article grant checklist** (next slide)
- **Assess each of the review criteria**
  - Write up strengths and weaknesses of each
  - Give a separate score for each (score should reflect your comments)
- **Provide an overall impact score which is separate from individual section scores**
- **Keep tone honest, helpful and constructive**

CHECKLIST FOR APPROACH

(Annals article Table 2, Pg. 279)

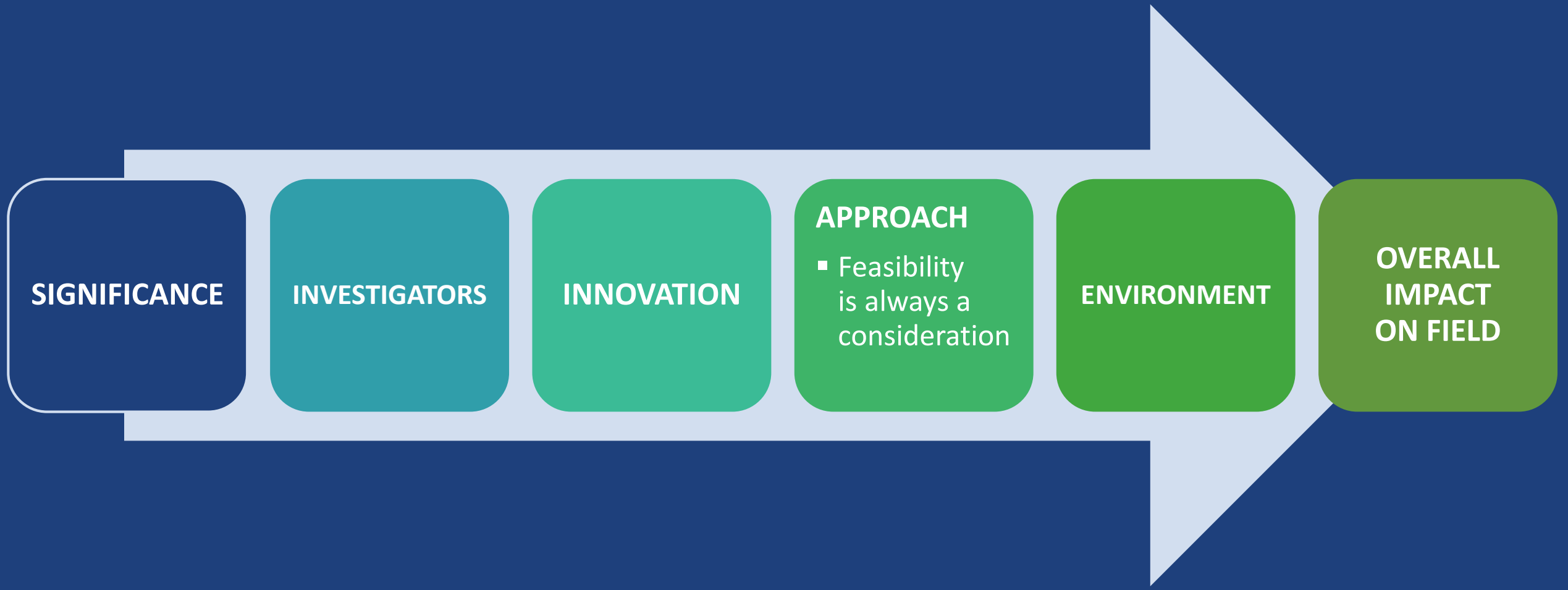
- Specific aims / hypotheses
- Background / significance
- Preliminary studies
- Methods
  - Study design / study sample
  - Data collection procedures
  - Outcome(s)
  - Intervention (if applicable)
  - Data analyses / sample Size (power)
- Strengths and limitations

SCORING TABLE FOR RESEARCH GRANTS

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
MODERATE	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

Use full range of scores for our grants, no ‘grade inflation’

NIH REVIEW CRITERIA



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, or clinical interventions in the field?

WILL THE WORK ADVANCE THE FIELD?

INVESTIGATORS

Focus on the qualifications and expertise of the members of the research team for the work proposed

Do they have the expertise to do the proposed work?

If the applicant is junior level, do they have appropriate experience and training?

Have they lined up the appropriate team to help?

If established, do they have a track record in the area? NIH funding?

If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise and are the roles clear?

INNOVATION

Is the application novel or does it improve previous work? work proposed

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel concepts, approaches, or methodologies?

APPROACH

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems/challenges, 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?

FEASIBILITY

Is the project overly ambitious?

Can the aims be achieved?

Is there convincing evidence that the work can be done (e.g., pilot testing)?

- Within the timeline stated?
- Within the budget given?

ENVIRONMENT

Will the scientific environment contribute to the probability of success?

Are the institutional support, equipment, and other resources adequate for the project?

Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

OVERALL IMPACT

Likelihood for the project to exert a sustained, powerful influence on the research field involved

Assessment of the strengths and weaknesses outlined for each of the five scored criteria

An application does not need to be strong in all categories to be judged likely to have major scientific impact

Overall Impact:
The likelihood that a project will have a sustained and powerful influence on science (and/or clinical practice and/or technological developments?)

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment)

e.g. Applications are addressing a problem of high importance in the field. May have some or no technical weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

Ref: http://grants.nih.gov/grants/peer/guidelines_general/scoring_guidance_research.pdf

EXAMPLES

SAMPLE
STRENGTHS

SIGNIFICANCE

This application is significant because there is little currently known about the direct and indirect costs associated with XYZ clinical condition and treatment.

Apathy in Alzheimer's disease and related dementia patients (ADRD) is a large problem and can be often miss-diagnosed as depression.

If successful the findings could lead to improvement in recognition of delirium in the clinical care of hospitalized older adults

SAMPLE
STRENGTHS

INVESTIVATORS

The collaborators in the team bring in additional expertise in imaging techniques. The collective level of expertise of this group is a great strength.

There is a long history of strong collaborations and publications among the team members.

Has strong bio statistical support as well as MS level biostatistician working with a top delirium investigative team

Reference: http://public.csr.nih.gov/ReviewerResources/GeneralReviewGuidelines/Documents/CSRCritqueExamples080411.pdf

SAMPLE
STRENGTHS

INNOVATION

- *Most methodology is relatively standard for the chosen experimental systems, but the concepts are highly novel.*
- *Concept of X control of a stress response is a novel hypothesis that will move the field forward.*

APPROACH

- *The study is hypothesis-driven, well-described, and has a high likelihood to generate new information on how Y modulates Z activity.*
- *The research design (convergent mixed method) is appropriate for this setting and population to enable rigor and reduce attrition, using qualitative and quantitative methods is a strength for this study.*

ENVIRONMENT

- *The investigator has established effective collaborations with experienced investigators both within and outside of their home institution which will provide the needed technologies.*
- *The principal investigator and investigative team have successfully collected data from this site in the past.*

Reference: http://public.csr.nih.gov/ReviewerResources/GeneralReviewGuidelines/Documents/CSRCritqueExamples080411.pdf

SAMPLE
WEAKNESSES

SIGNIFICANCE

- *Outcomes presented and the discussion of its significance in the application indicates a lack of understanding of Q cell development.*
- *It would be surprising if a simple dietary supplement in isolation were to have an effect as profound as that which is hypothesized.*

INVESTIGATORS

- *A bio statistical consultant will participate only at the end of the study for analysis of the acquired data. There is a concern that this service may be needed at earlier stages of the study as well.*
- *The need for the other collaborators listed as subcontracts is unclear. There is no information or justification provided as to what these collaborators will be doing.*
- *The addition of an implementation scientist would be helpful*
- *A senior scientist with expertise in X is lacking on the team…*

Reference: http://public.csr.nih.gov/ReviewerResources/GeneralReviewGuidelines/Documents/CSRCritqueExamples080411.pdf

SAMPLE
WEAKNESSES

ENVIRONMENT

Samples will have to be shipped for subsequent analysis and, given the circumstances, there is a higher than normal risk of losing samples.

There is no documentation or letters of support from the appropriate authorities giving permission to conduct the study at the chosen site.

Reference: http://public.csr.nih.gov/ReviewerResources/GeneralReviewGuidelines/Documents/CSRCritqueExamples080411.pdf

SAMPLE WEAKNESSES

INNOVATION

- *A large body of research already exists on organizational readiness for change.*
- *Psychometrically sound measures of organizational change exist. Adaptation to the proposed clinical environment represents only minor innovation.*

APPROACH

- *Some of the data interpretation is discussed in generalities and mainly focuses on how studies would confirm what has already been published.*
- *It is unclear how the measurements the PI proposes would further our understanding of the proposed problems.*
- *It is unclear that an adequate sample and enrollment strategy is available. Data should be provided showing the potential pool and strategies…*
- *The RA training, fidelity, inter-rater checks, blinding and rigor of measures are not described for the important outcomes and assessments*

Reference: http://public.csr.nih.gov/ReviewerResources/GeneralReviewGuidelines/Documents/CSRCritqueExamples080411.pdf

COMMENTS

FOR NEW OR EARLY STAGE INVESTIGATORS

- *This application is overly ambitious…a common mistake for junior investigators. This investigator would be wise to develop fewer aims more thoroughly. It's always risky to base subsequent aims on the outcome of the first one.*
- *The application creates the impression that the new investigator is rather isolated intellectually. It appears that s/he would benefit from mentorship and interactions outside of his/her institution. These should be available locally and be clearly stated how they will work together.*

Reference: public.csr.nih.gov/aboutcsr/NewsAndPublications/PeerReviewNotes/Pages/Peer-Review-Notes-September-2012part3.aspx

ON GRANT WRITING ISSUES

COMMENTS

- *This application contains extensive jargon that is not defined and experiments that are not linked to specific aims (see Annals article—everything should flow from the aims!)*
- *A thorough rewrite with the help of an experienced grant writer is suggested before this application is resubmitted*

Reference: public.csr.nih.gov/aboutcsr/NewsAndPublications/PeerReviewNotes/Pages/Peer-Review-Notes-September-2012part3.aspx

SCIENTIFIC RIGOR AND PREMISE

RIGOR (research approach)

Use of the scientific method, adequate power, controls and reduction of bias (approach)

PREMISE (supporting data and gaps)

- *Refers to the quality and strength of the prior research used as the basis for the proposed research question or project*
- *Strengths and weaknesses of prior work and how this will address the gaps (significance)*

SCIENTIFIC RIGOR AND PREMISE

SCIENTIFIC PREMISE

- *Reviewers must consider the scientific foundation for the proposed work*
- *Are the preliminary studies and prior research on which the study is based sound?*
- *Not the same as study significance or reasonableness of hypotheses. But about the quality of the supporting evidence.*
- *Rated as part of "Significance"*
- ***Does** influence overall score*

SCIENTIFIC RIGOR AND PREMISE

RIGOR AND TRANSPARANCY

Relatively New NIH Reviewer Criteria Specifications

- *Scientific Premise (in Significance)*
- *Scientific Rigor (in Approach)*
- *Relevant Biological Variables such as sex*
- *Authentication of materials*

SCIENTIFIC RIGOR AND PREMISE

SCIENTIFIC RIGOR

- *Reviewers are asked to comment on and base scoring on the methods to ensure the study design is:*
  - *Unbiased*
  - *Sound and rigorous methodology*
- *Part of "Approach" rating*
- **Does** *influence overall score*

RELEVANT BIOLOGICAL VARIABLES

- *Both males and females should be included*
- *At a minimum, plan for presentation of results in a sex-stratified*
- *Does not necessarily mean adequate power is needed to test main or modification effects by sex.*
- ***Does** influence overall score*

See source: *http://grants.nih.gov/grants/peer/guidelines_general/SABV_Decision_Tree_for_Reviewers.pdf*

WHAT HAPPENS AT BOOTCAMP

?

- *Goal is to function like an NIH Study Section*
- *For each grant, first reviewer will present a brief synopsis of the grant, and major comments*
- *Second reviewer will add any additional points*
- *Alumni reviewer will add comments*
- *Faculty reviewer will highlight some key points and summarize*
- *The grantee will receive written comments from all reviewers*
- *The grantee will be a "fly on the wall"- though they can ask questions later 1:1 at lunch or in networking sessions*

TAKE HOME TIPS

- Remember it is both an art and a science!
- Be constructive
- Be kind
- Have fun

THANK YOU

Good science depends on reviews and peer support!

QUESTIONS?

(Slides adapted in 2017 from Sharon Inouye)