WHAT REALLY HAPPENS IN AN NIH STUDY REVIEW

Paul J. Martin, MD
ITHS
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WELCOME TO THE CAREER DEVELOPMENT SERIES

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We love to hear from you!

Please connect anytime.

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Paul J. Martin, MD

Dr. Martin is a medical oncologist who specializes in treating patients with bone marrow transplantation. Dr. Martin is Co-PI of ITHS, a member of the Clinical Research Division at Fred Hutch, Director of the Fred Hutch Research Trials Office, and a professor in the Medical Oncology Division at the University of Washington School of Medicine.
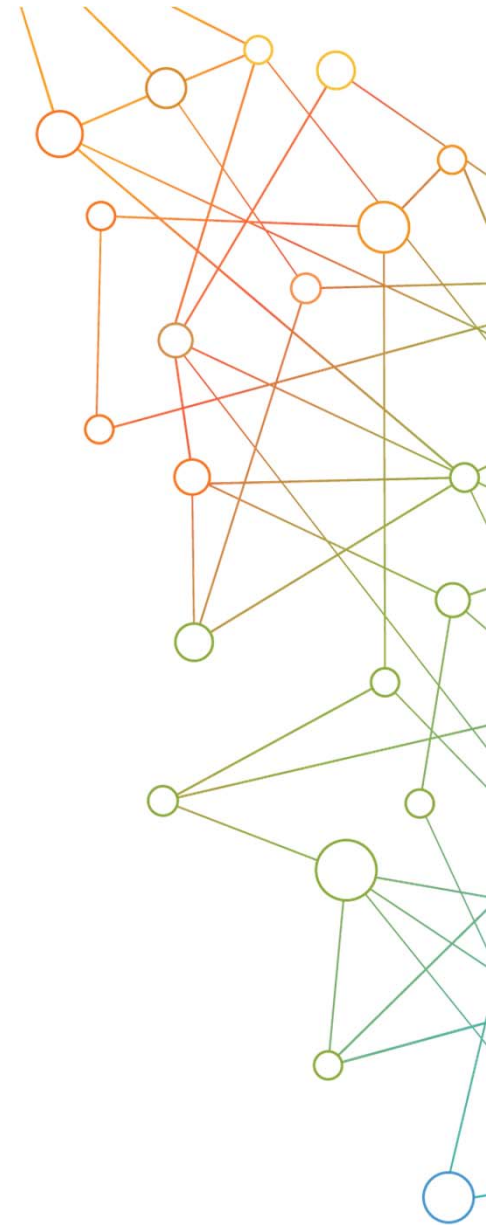
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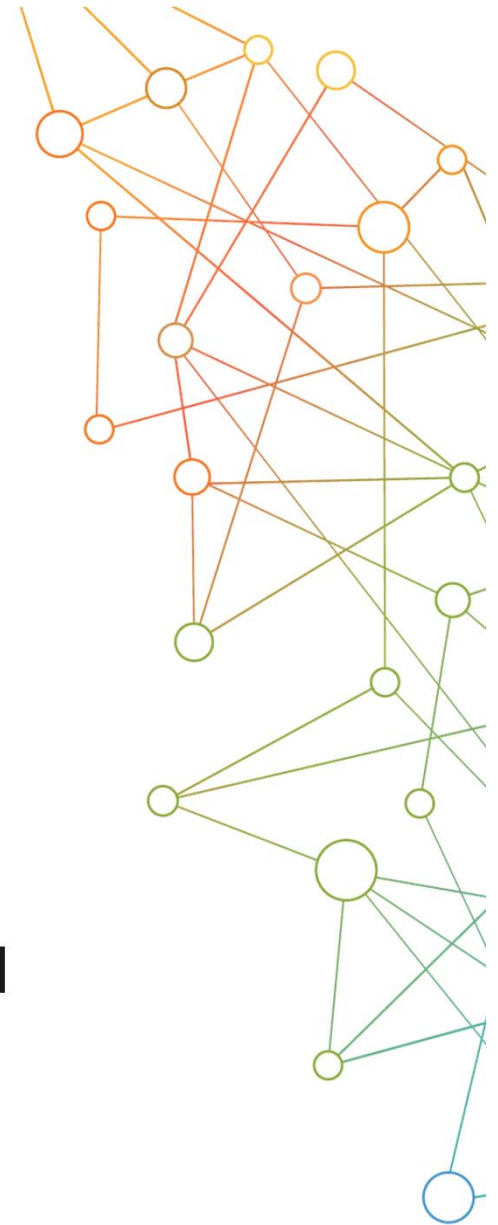
Overview
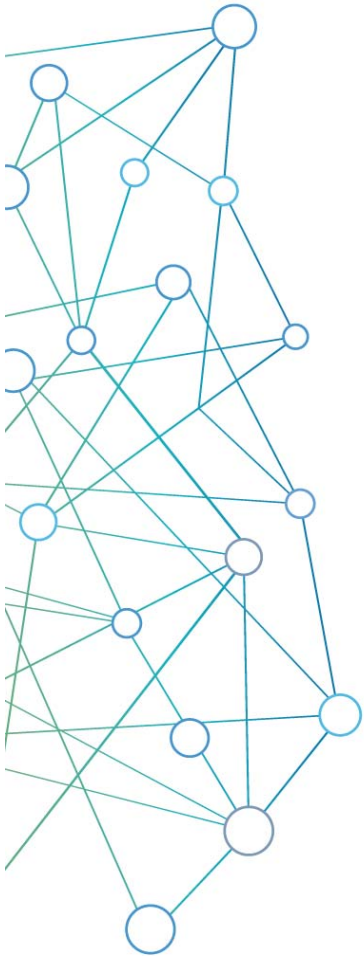
- What happens at the meeting
- Summary of recent changes
- Review criteria
- "Impact" vs. "Significance"
- Review scoring
- Advice from NIH
- Important writing tips
- Frequent mistakes
- Advice from retired study section chairs
- Where to get more information

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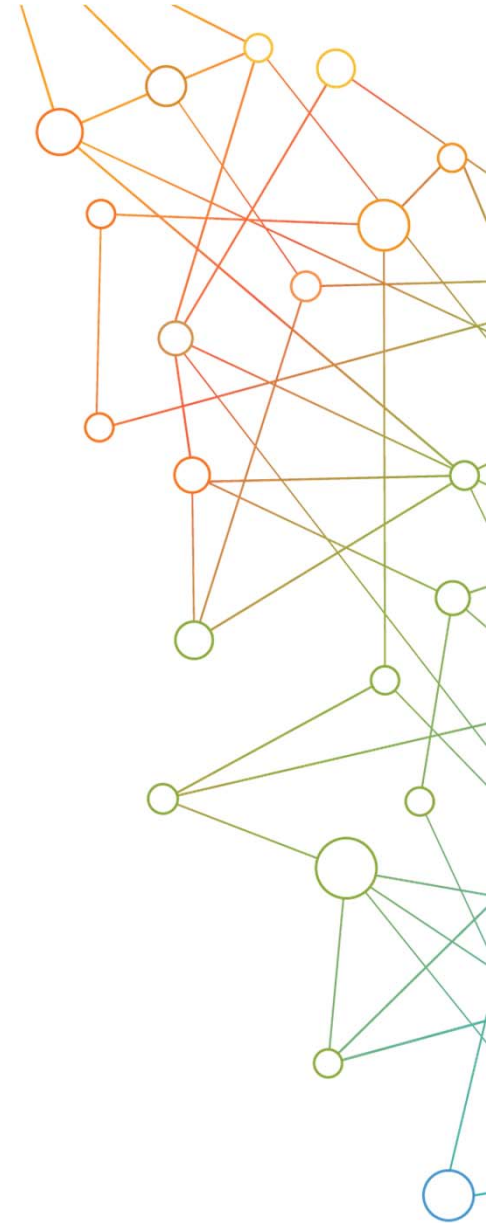Accelerating Research. Improving Health.

Overview of the Meeting

- Welcome and call to order by chair

- Panel members introduce themselves

- Introductory remarks and instruction by SRO

- Order of review

  - New investigator R01 applications

  - Other R01 applications

  - R21 applications

- Order determined by average of preliminary overall scores from assigned reviewers

- ~ 50% of applications are discussed

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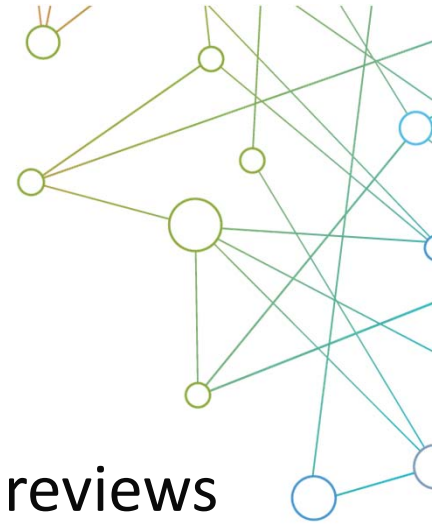Accelerating Research. Improving Health.

How Reviews are Discussed

- Conflicted members leave the room

- Applicant and title announced by chair

- Preliminary overall scores from reviewers

- Discussion by primary reviewer

- Additional comments by other reviewers

- Human subjects and animal welfare concerns

- Panel discussion

- Summary by chair

- Revised overall scores announced

- Voting outside range

- Budget recommendations

- Conflicted members called back

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Summary of Recent Changes
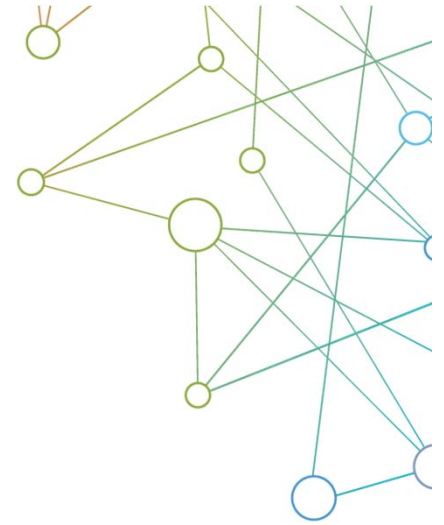

► Emphasis on "impact"

► Bullet point format of reviews

► Tutorial comments not encouraged

► Discussion ordered by preliminary score

► New investigator applications separated

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Scored Review Criteria

- ▶ Impact
- ▶ Significance
- ▶ Investigators
- ▶ Innovation
- ▶ Approach
- ▶ Environment

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Impact

- Summarize significant overall strengths and weaknesses

- Assess the likelihood that the project will exert a sustained powerful influence on the field

- Feasibility is an important consideration

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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 or clinical practice be improved?

- How will successful completion of the aim change the concepts, methods, technologies, treatments, services or preventive interventions that drive this field?

Investigator

- Are the researchers well suited to the project?

- If Early Stage or New Investigators (only R01), do they have appropriate experience and training?

- If established, have they demonstrated an ongoing record of accomplishments that have advanced their fields?

- If the project is collaborative or multi-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 or novel in a broad sense?

- Is it a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation or interventions proposed?

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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?
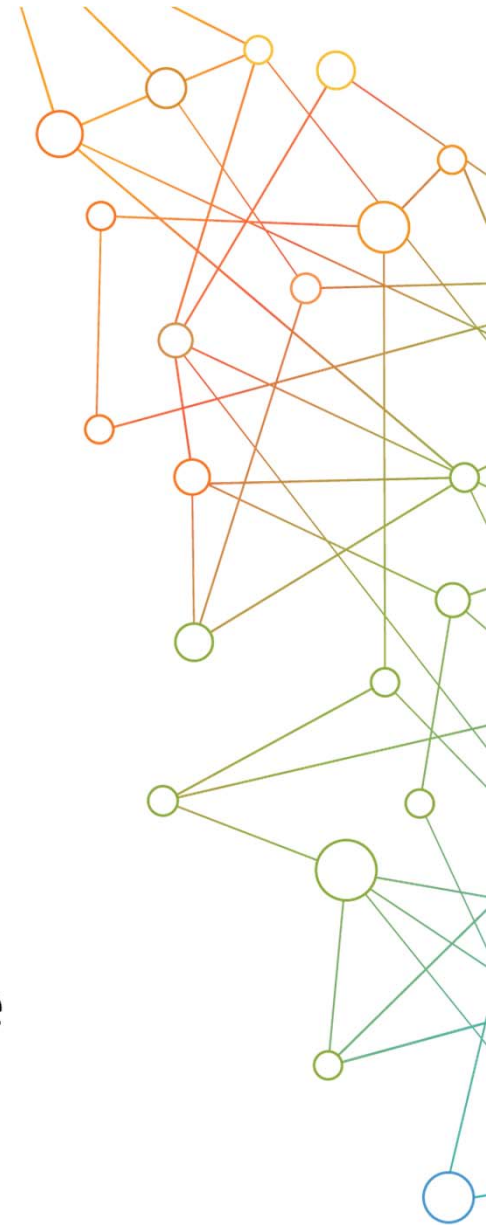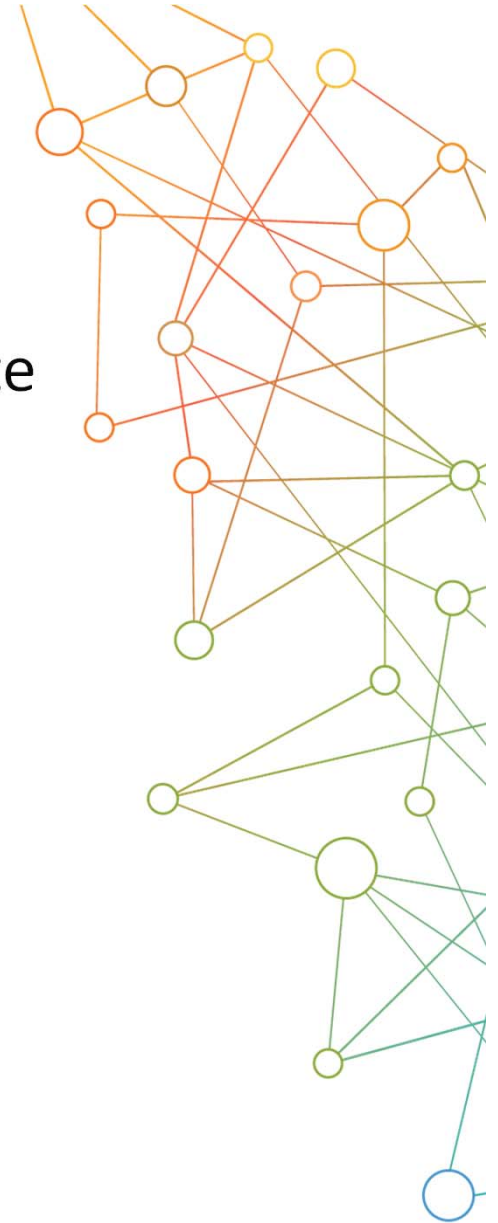
Additional Review Criteria*
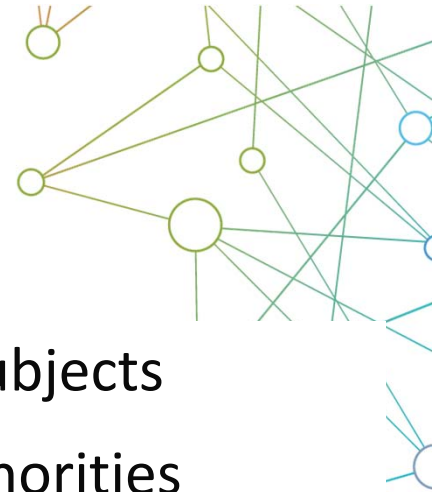
▶ Protection for human subjects

▶ Inclusion of woman, minorities and children

▶ Vertebrate animals

▶ Biohazards

▶ Resubmission

▶ Renewal

▶ Revision (competing supplement)

▶ Multiple PI plan

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*can affect overall score

Protection for Human Subjects*

- Evaluate risks as acceptable or unacceptable

- Evaluate protections as adequate or inadequate

- Items for evaluation

  - Risk to subjects

  - Adequacy of protection against risks

  - Potential benefits to subjects and others

  - Importance of the knowledge to be gained

  - Data and safety monitoring for clinical trials

  - Data and Safety Monitoring Plan

  - Justification for exempt status

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*can affect overall score via "approach"

Inclusion of Women, Minorities and Children*

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender Unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

A = Acceptable; U = Unacceptable

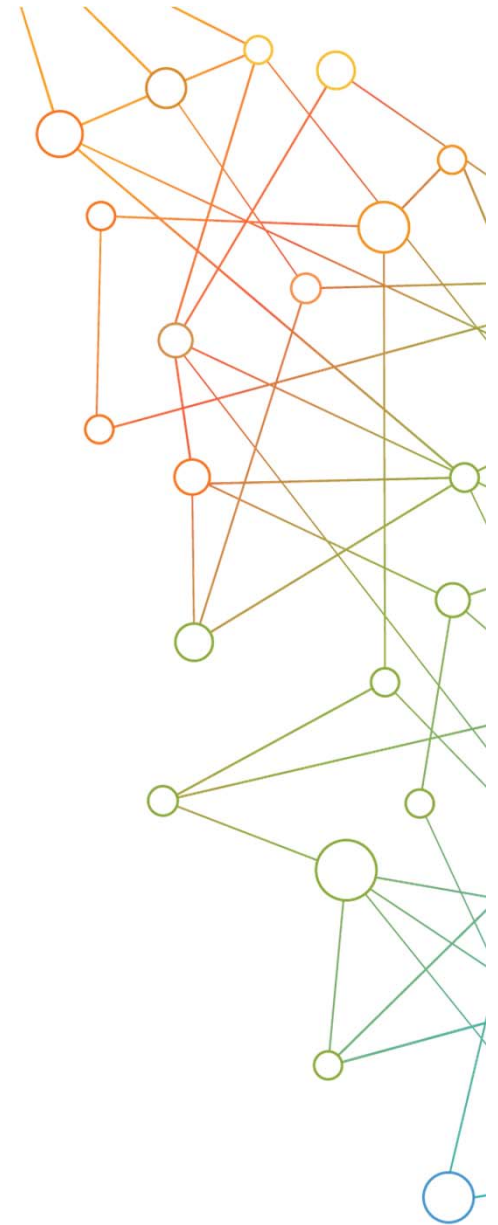*can affect overall score via "approach"

Vertebrate Animals*

- Evaluate as acceptable or unacceptable
  - Proposed use of animals
  - Species, strains, ages, sex and numbers
  - Justification for use of animals and for appropriateness of the species and numbers proposed
  - Adequacy of veterinary care
  - Procedures to limit discomfort, distress, pain and injury
  - Methods of euthanasia
- Worksheet available from CSR website

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*can affect overall score via "approach"

Additional Review Considerations*

- Application from foreign organizations

- Select agents

- Resource sharing plans

- Data sharing

- Model organisms

- Genome-wide association studies

- Budget and period of support

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*do NOT affect overall score

"Impact" vs. "Significance"

► Three key phrases for "Impact"

  ► Likelihood—derived from assessment of investigator, approach and environment

  ► Sustained powerful influence—derived from significance and innovation
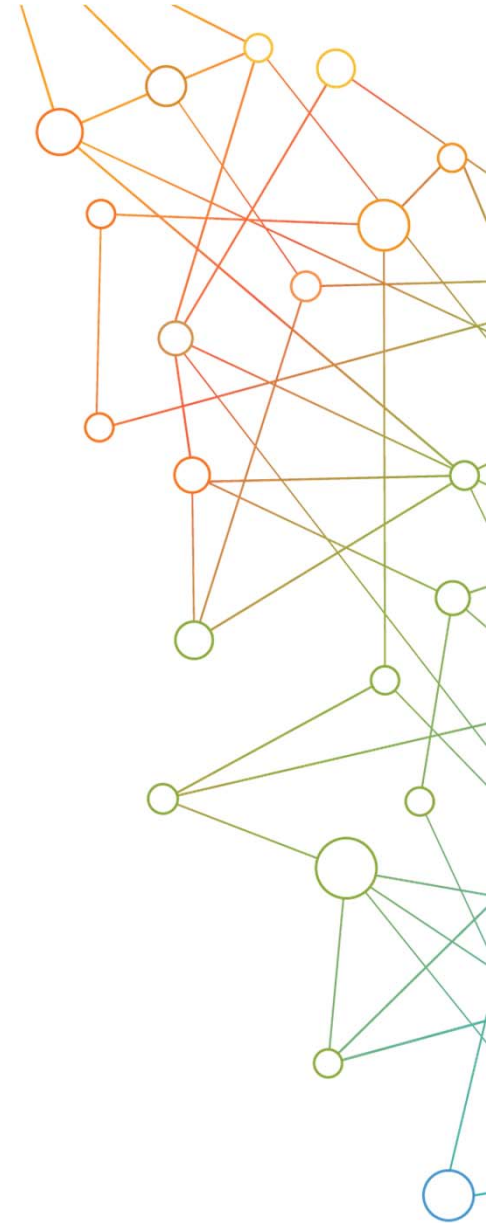
  ► Research field—should be identified

► "Impact" is not

  ► a 6th review criterion

  ► the mean of scored criteria

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"Cheever Types"

- Type 1
    - project is important
    - applicant is able to do the work

"Cheever Types"

- Type 1
  - project is important
  - applicant is able to do the work

- Type 2
  - project is important
  - applicant not able to do the work

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"Cheever Types"

- Type 1
  - project is important
  - applicant is able to do the work

- Type 2
  - project is important
  - applicant not able to do the work

- Type 3
  - project not important
  - applicant is able to do the work

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"Cheever Types"

- **Type 1**
  - project is important
  - applicant is able to do the work

- **Type 2**
  - project is important
  - applicant not able to do the work

- **Type 3**
  - project not important
  - applicant is able to do the work

- **Type 4**
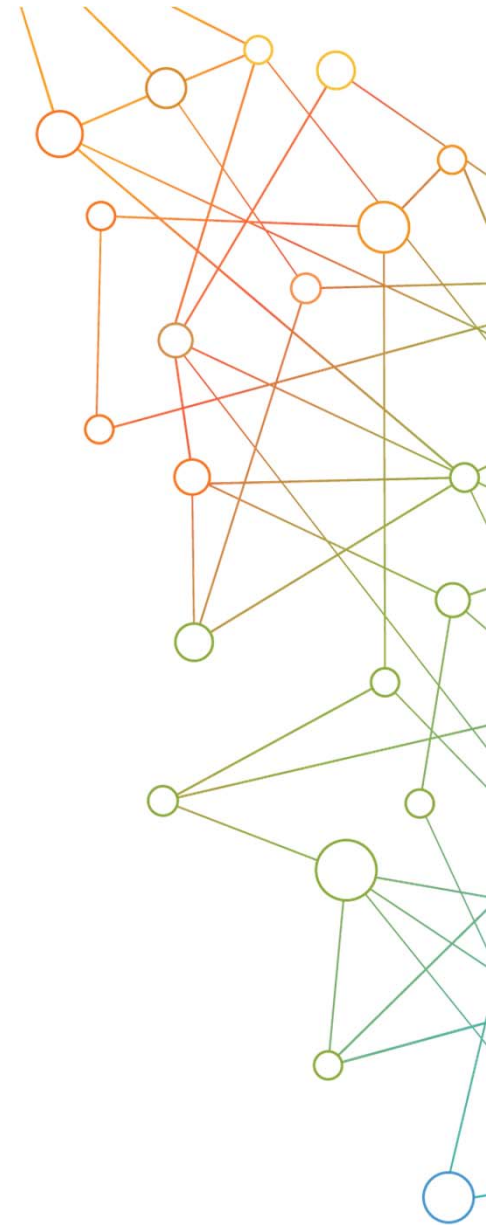 - project not important
  - applicant not able to do the work

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Review Scoring

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

Categories of Weakness

- Minor
  - An easily addressable weakness that does not substantially lessen impact

- Moderate
  - A weakness that lessens impact

- Major
 - A weakness that severely limits impact

Budget and Period of Support

- Is the budget realistic?
- Reductions can be recommended
    - Insufficient budget justification
    - Insufficient information about work in later years
    - Project can be completed in fewer years or with smaller budget
- Panel recommendation summarized by SRO
- Budget does not affect overall priority score
- Overlap concerns noted in written comments (not discussed)

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Additional Comments to Applicant

- Elaboration of ideas that are too complex for bullet points

- Further explain deficiencies in the application
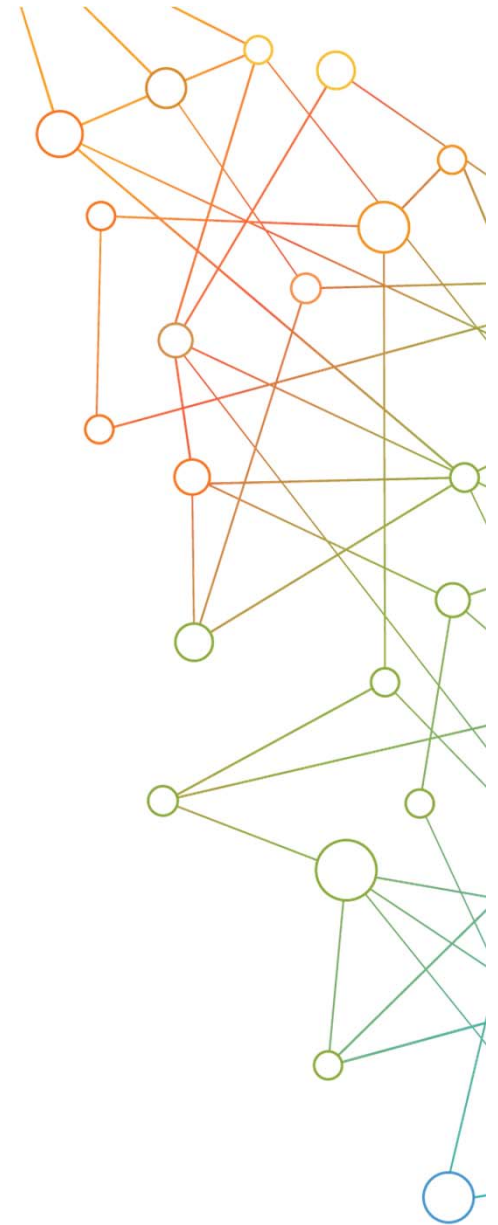
- Avoid "tutorial" suggestions for improvement

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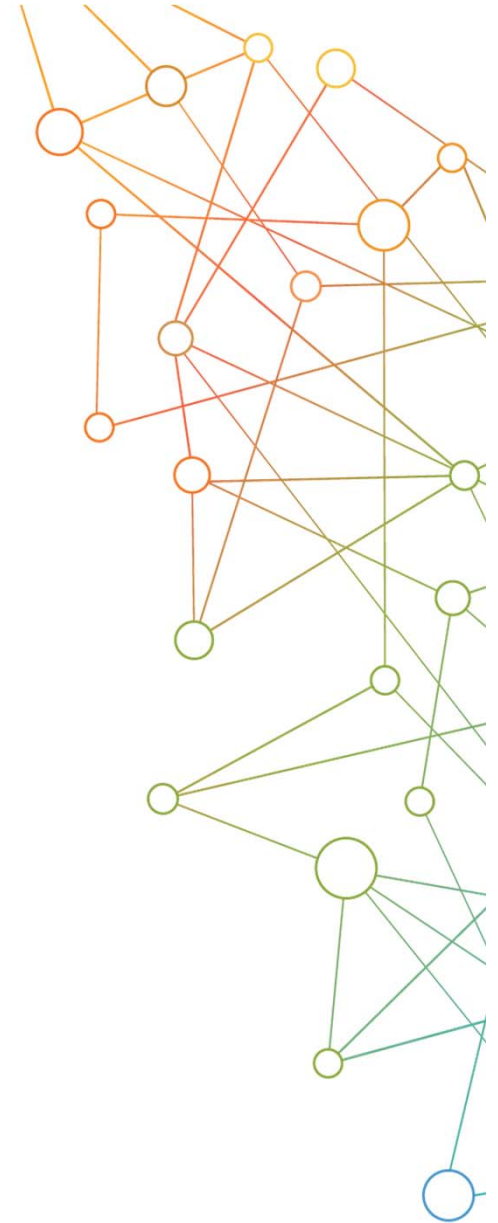
Advice from NIH:
Write to Your Audience

- "Play to the house"
  - Strong potential to have high impact
  - Logical and innovative approach
  - Institutional support
  - Personal and team expertise
  - Project is a worthy investment
- "Write for your assigned reviewers"
  - Aims do not duplicate other work
  - Aims and significance clearly state impact
  - Work will add significantly to existing knowledge
  - Expertise documented in biosketches
 - Resources well documented

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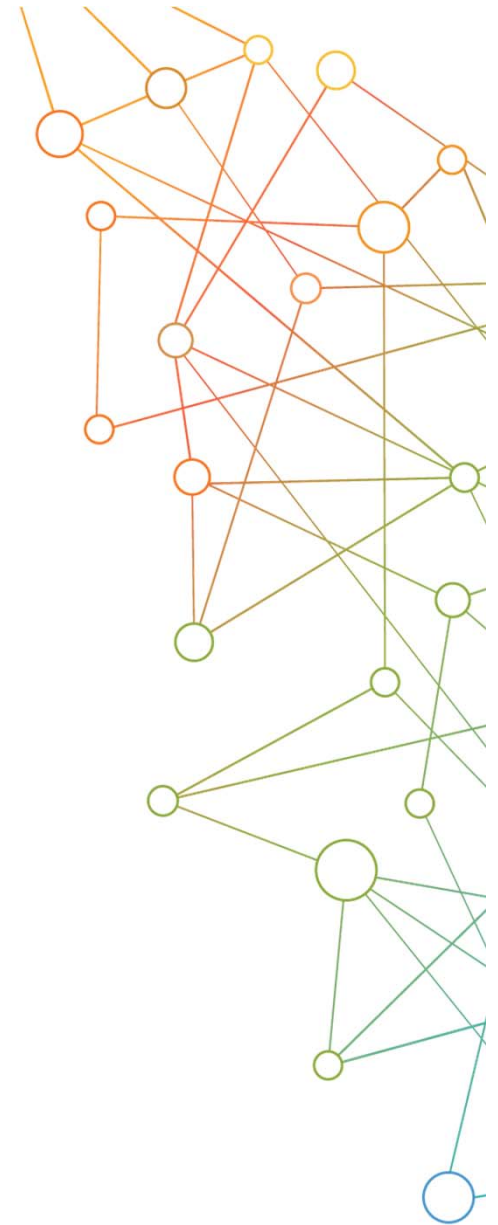
Advice from NIH:
Write to Your Audience

- "Don't neglect others"
  - Abstract, Specific Aims, Significance
  - Written like a *Scientific American* article

- "Investigate committees and members"
  - Committee with people who will appreciate the work
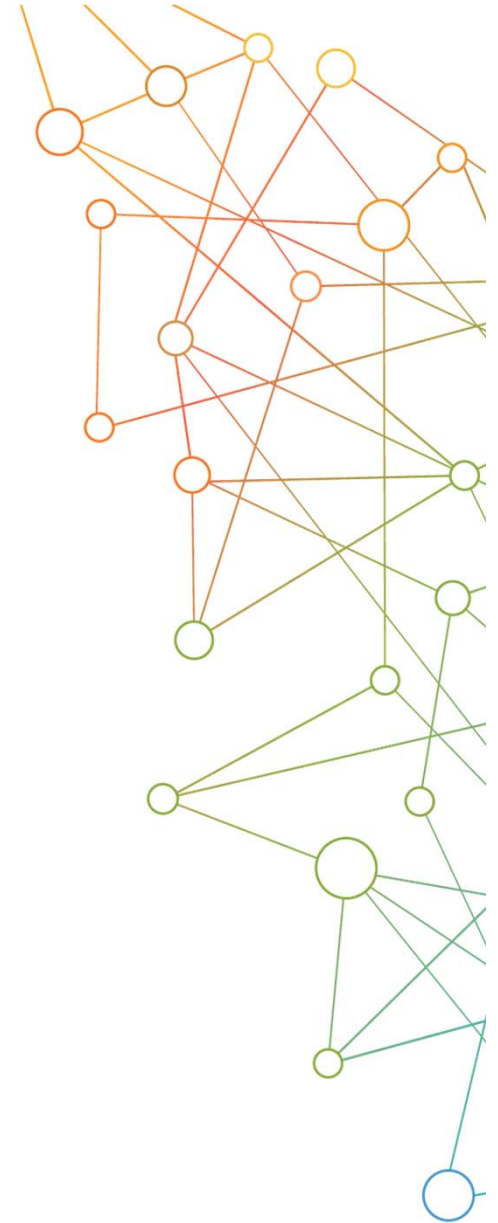 - Examine their publications
  - Understand their perspective

Advice from NIH:
Caution with Innovation

- Show how research is new and unique
  - Challenge an existing paradigm
  - Data to support an innovative approach
  - Evidence that approach is feasible
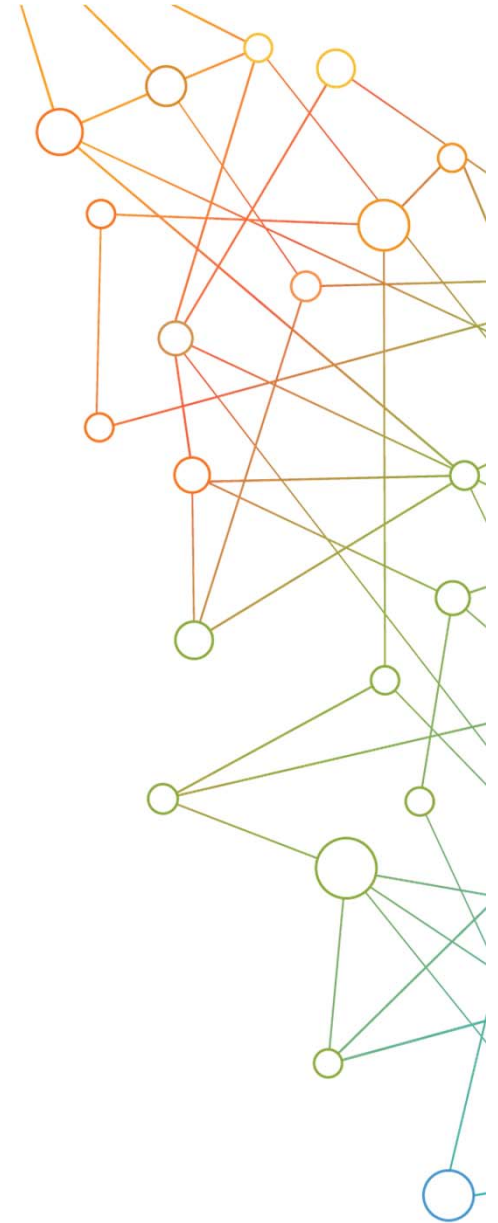
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- **Existing concept or method**
  - Refined
  - Improved
  - New application or use

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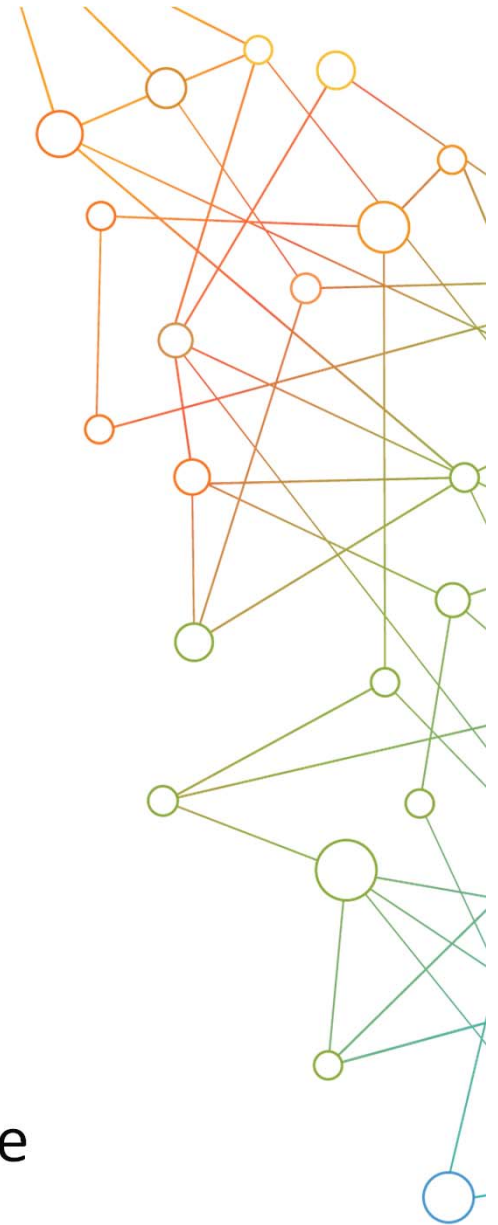Accelerating Research. Improving Health.

Advice from NIH: Master the Application

- Page limits, formats

- Write, Edit and Proof like a professional
  - User-friendly format
  - Well organized
  - Visually appealing

- Make a positive first impression
  - Divide into sections
  - Guide concepts with graphics
  - Label all materials clearly
  - Edit and proofread

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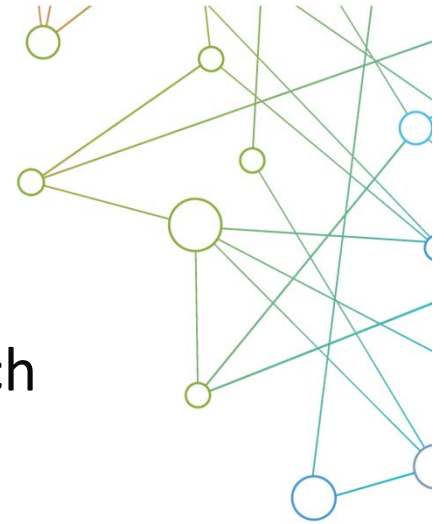Accelerating Research. Improving Health.
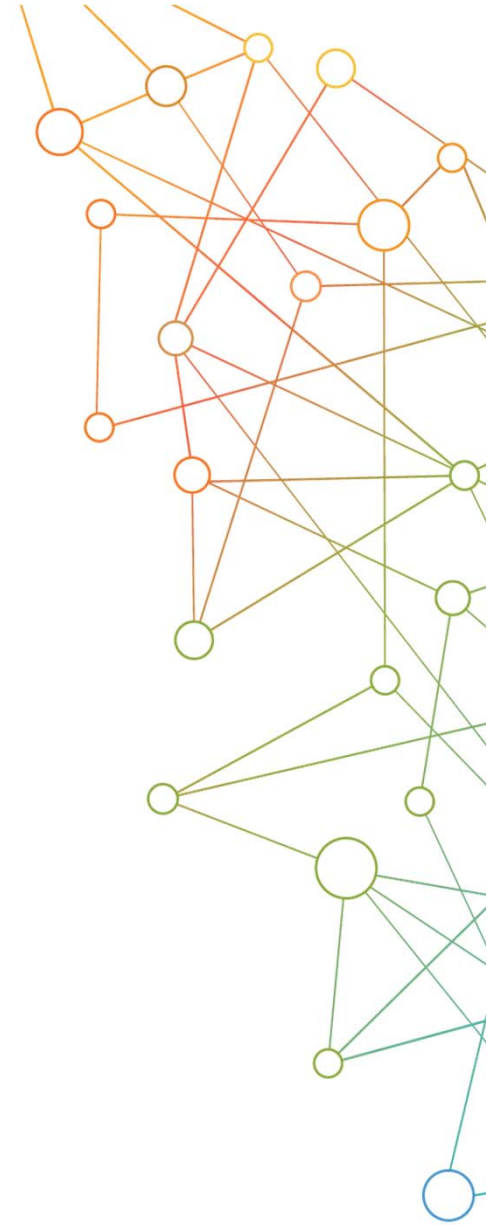
Advice from NIH: Get Prepared

- Read and follow instructions

- Feedback from colleagues

- Work from an outline

- Must have adequate data

- Leave enough time to write application

- Review examples from successful applicants

- Make sure that the idea is original

- Assess the competition

- Refine ideas to ensure that the work is feasible

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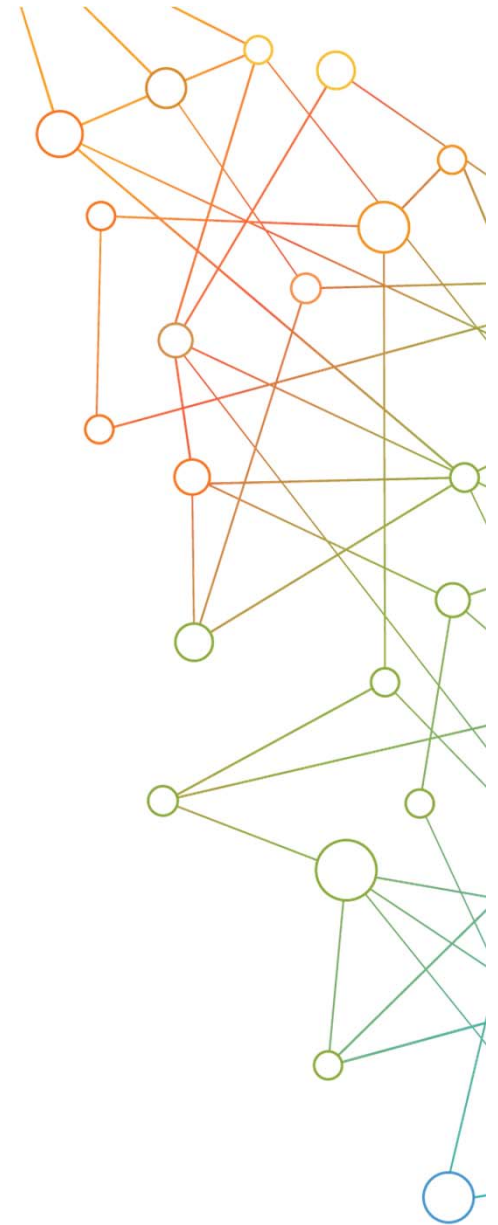Accelerating Research. Improving Health.

Important Writing Tips

- ▶ A topic sentence for each main point
- ▶ One point for each paragraph
- ▶ Keep it short and simple
- ▶ Progress from basic to complex
- ▶ Use nontechnical language, where feasible
- ▶ Use short sentences (20 words or less)
- ▶ Use transitions to link points together

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Frequent Mistakes

- Study not likely to produce useful information

- Hypothesis or data not well founded

- Alternative hypotheses not considered

- Methods not appropriate

- No significant impact on health

- Too little detail

- Over-ambitious research plan

- Direction and priorities not well defined

- Lack of focus in hypothesis, aims or plan
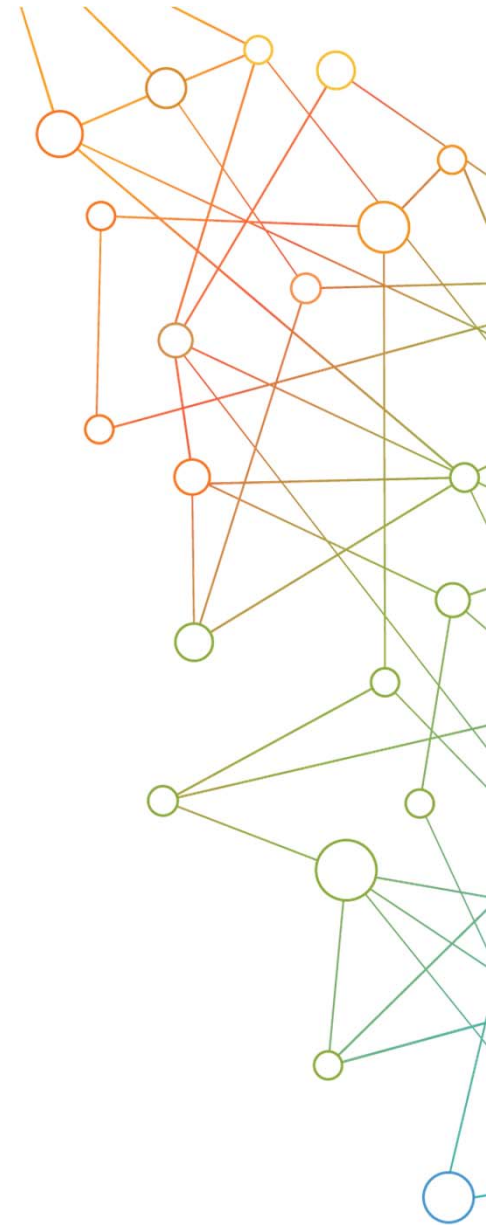
- Lack of original or new ideas

Frequent Mistakes—Continued

- Investigator not sufficiently experienced

- Problem more complex than PI realizes

- Experiments or model not relevant to hypothesis

- Topic scientifically premature

- Fishing expedition lacking scientific basis

- A method in search of a problem

- Interdependent aims (one fails, all fail)

- Inadequate controls

- Feasibility not demonstrated

- Insufficient consideration of statistical needs

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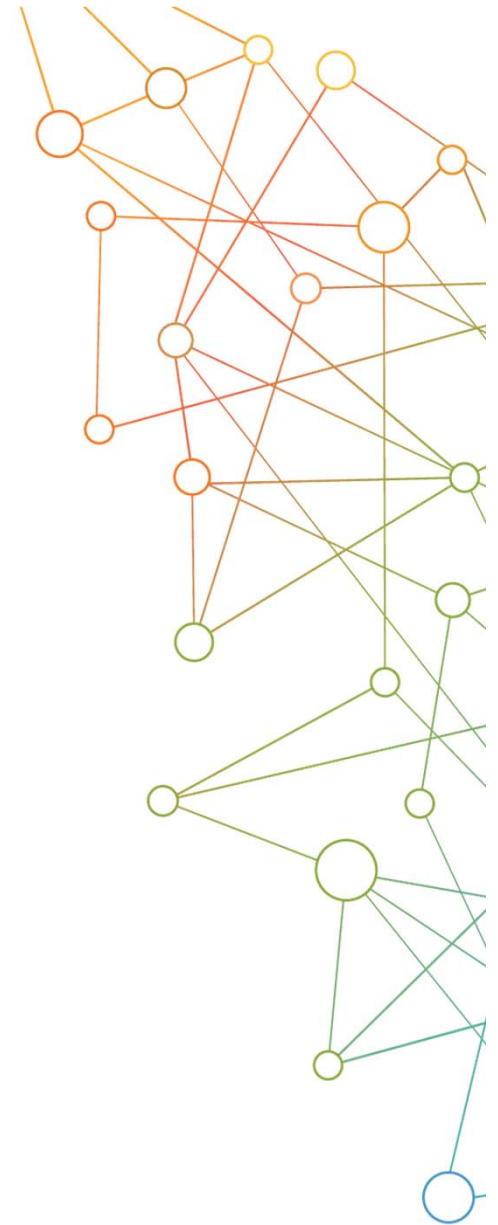Accelerating Research. Improving Health.

Advice from Retired Study Section Chairs

- Propose something significant

- Make it exciting

- Probe for mechanisms and seek new models

- Don't just "collect more data"

- Be very clear and concise
  - What you want to do
  - Why it's important
  - What you expect to get out of it

- Don't assume too much expertise in reviewers

- Be brief with stuff everyone knows

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Advice from Retired Study Section Chairs

- Aim each aim
    - Expected outcomes
    - Data interpretation
    - Pitfalls and alternatives
- Summarize the take-home message at the end
- Start the writing with Specific Aims
- Submit best effort first
- Don't cram the application like a suitcase
- Proofread your application
- Be persistent

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Where to Get More Information

**About writing applications
NIAID "New Investigator Series"**

http://funding.niaid.nih.gov/researchfunding/grant/pages/newpiportal.aspx#nl

http://cms.csr.nih.gov "Insider's Guide to Peer Review For Applicants"

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Thank You