What We Offer:

1 **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

2 **Community Engagement:** Members can connect with regional and community based practice networks

3 **Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

4 **Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

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Contact our Director of Research Development

- Project Consultation

- Strategic Direction

- Resources and Networking

Melissa D. Vaught, Ph.D.
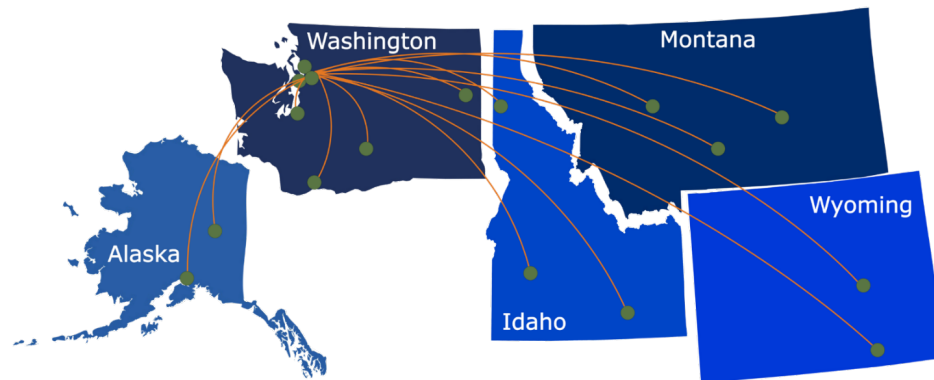**ithsnav@uw.edu**
206.616.3875

Upcoming Career Development Series 2021

April 14, 2021 – The Ins and Outs of Being a Research Good Mentor

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April 22, 2021 – Acknowledging and Rewarding Interdisciplinary Research within Appointment, Promotion and Tenure Processes

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May 4, 2021 – Implicit Bias in Health Care and Research

May 12, 2021 – Evidence Synthesis Primer (Part 2 of 2)

June 9, 2021 – Remote Consenting During the Time of COVID

June 29, 2021 – SOLO-ing Together: The Seat of Learning Opportunity for Developing Conflict Management Skills

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Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

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Learning Objectives

1 Understand how a study section works and what grant reviewers are looking for in a grant.

2 Understand the sections of an NIH grant and how the grants are scored

3 Understand the importance of stated hypotheses, rigor and reproducibility and authentication

Overview

- Reviewer instructions
- 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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Reviewer Instructions

►Emphasis on "impact"

►Bullet point format of reviews

►"Tutorial" comments not encouraged

Scored Review Criteria

- ►Impact
- ►Significance
- ►Investigators
- ►Innovation
- ►Approach
- ►Environment

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?

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

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

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

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Additional Review Criteria*

- ►Protection for human subjects
- ►Inclusion of woman, minorities and children
- ►Vertebrate animals
- ►Biohazards
- ►Resubmission
- ►Renewal
- ►Revision (competing supplement)
- ►Multiple PI plan

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

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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

can affect overall score via "approach"

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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Responding to Reviewers

- Write the response first
    - Focus on score-driving comments (i.e., resume)
    - Do clarify facts
    - Do not argue or complain

- Then revise the application
    - Use draft response as outline, BUT
    - Do not slavishly follow suggestions from reviewers
    - Focus on changes to improve the success of the project
    - Emphasize new preliminary data, if available

- Rewrite the response
    - Explain how the revised application has been improved
    - Delete any vestigial negative or hostile tone

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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
  - Document expertise in biosketches
  - Document resources available to support the work

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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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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

- Existing concept or method

  - Refined

  - Improved

  - New application or use

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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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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

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

What is a Specific Aim?

- ►Something I will do?
- ►A goal?
- ►A search for hypotheses?
- ►A test of some hypothesis?

What Does Hypothesis Mean?

► A notion of reality that is

- ► Plausible
- ► Not fully established
- ► Testable
  - ► Makes specific predictions
  - ► Can be falsified or can falsify other hypotheses

How to Build a Case

- ►Title of the Aim
  - ►Rationale
    - ►Fact 1
    - ►Fact 2
    - ►Fact 3
    - ►Deduced hypothesis
  - ►Experiments to be done
  - ►Expected results, pitfalls, alternatives, future directions

A Better Way to Build a Case

- ►Title of the Aim
  - ►Hypothesis
    - ►Supporting evidence
    - ►Conflicting evidence
    - ►Missing evidence
    - ►Implications
  - ►Experiments to be done
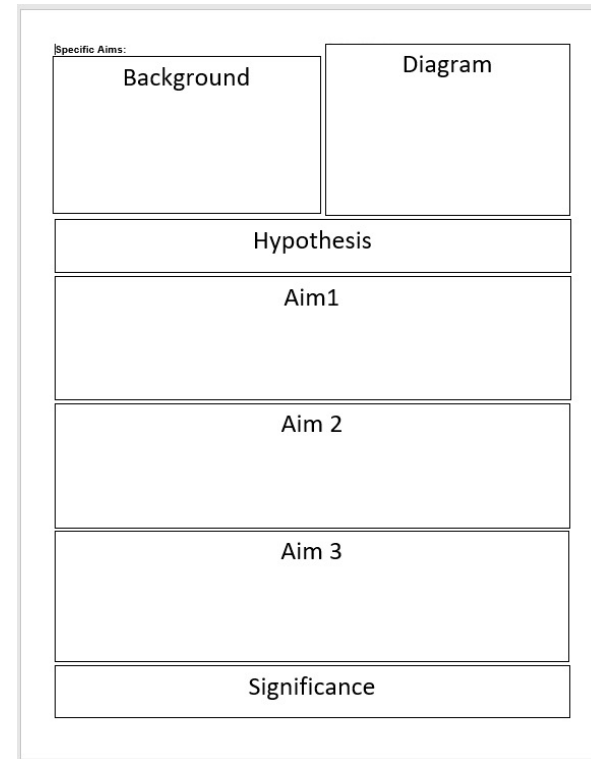 - ►Predicted results, pitfalls, alternatives, future directions
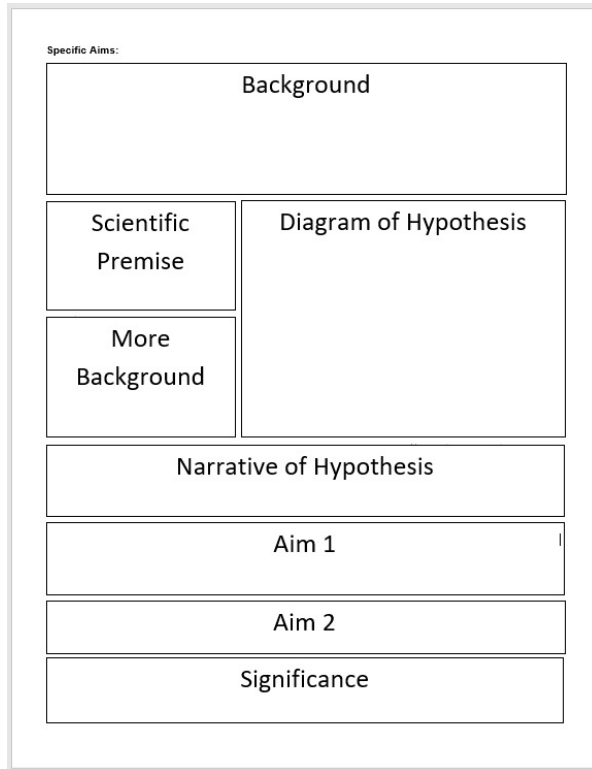
How to Invest Your Real Estate

Specific Aims:

Background

Scientific Premise	Diagram of Hypothesis
More Background	

Narrative of Hypothesis

Aim 1

Aim 2

Significance

How to Invest Your Real Estate

Left diagram:

Specific Aims:

Background

Scientific Premise

Diagram of Hypothesis

More Background

Narrative of Hypothesis

Aim 1

Aim 2

Significance

Right diagram:

Specific Aims:

Background

Diagram

Hypothesis

Aim1

Aim 2

Aim 3

Significance

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How We Want the Study Section Member to Feel

► The narrative in this application tells the story in an easily understandable, logical way

  ► That piques my interest in knowing the results of the proposed work (i.e., how the story ends) and

  ► Convinces me that the investigators can do the work.

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

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

Advice from Retired Study Section Chairs – Continued

- 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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Rigor and Reproducibility-Part 1

4 AREAS OF FOCUS	WHAT DOES IT MEAN?	WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?
Rigor of the Prior Research	A careful assessment of the **rigor of the prior research** that serves as the key support for a proposed project will help applicants identify any weaknesses or gaps in the line of research. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project *See related FAQs, blog post	**Research Strategy** ➢ Significance ➢ Approach
Scientific Rigor (Design)	**Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results. *See related FAQs, blog post, examples from pilots	**Research Strategy** ➢ Approach

https://grants.nih.gov/policy/reproducibility/guidance.htm

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Rigor and Reproducibility-Part 2

Biological Variables	**Biological variables**, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex. *See related FAQs, blog posts, article	**Research Strategy** ➤ Approach

https://grants.nih.gov/policy/reproducibility/guidance.htm

Authentication of Key Biological and Chemical Resources

"Key biological and/or chemical resources" refers to established reagents or resources that will be used in the proposed research

For example:
Applicants proposing to use cell lines could describe the method they plan to use to verify the identity and purity of the lines

Applicants proposing to use chemicals that are key to the research could describe the method used to validate the chemical, (e.g. mass spectrometry).

Applicants proposing to use genetically modified animals or cells could describe the method used to confirm the genome modification (e.g. PCR amplification)

Include as an attachment; not as part of the research plan

See--https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-068.html

Where to Get More Information

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

- https://www.niaid.nih.gov/grants-contracts/prepare-your-application

- https://public.csr.nih.gov/ForApplicants

Thank You!

Open for Questions

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Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.

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