

CHARM DATABASE SEMINARS

SESSION 4:

MONDAY, MAY 13, 2024

1. WRITING A SIGNIFICANCE SECTION
2. STUDYING BREAST FEEDING
(Vanessa Wandrie, MSc)

NEXT SESSION

- We'll take a summer break
- MARCH Seminar #5 will be held on **Monday, September 9th at 1 pm.**
- The topic will be on the sampling frame of MARCH, presented by Michael Elliott of U of M.

NIH WEBINAR THIS WEEK

NIH Grants Process: A Brief Walk-Through for Beginners

WEDNESDAY MAY 15 1 PM

This event offers participants an opportunity to gain insight into the NIH's organizational structure and how it funds research, resources to help find the right fit for your research including NIH Notices of Funding Opportunities (NOFOs), an overview of the grants process and peer review, NIH and applicant institution roles/responsibilities, and where to access help along the way.

<https://nih.zoomgov.com/webinar/register/WNHVuQzY1-QI-v1D-D9pFzBg#/registration>

COMPONENTS OF THE RESEARCH STRATEGY OF INVESTIGATOR-INITIATED APPLICATIONS TO NIH

- Specific Aims (covered in seminar 2)
- Research Strategy
 - Significance
 - Innovation
 - Approach

I'll talk about how to craft the **Significance** section today

THE FIVE CRITERIA FOR EVALUATING AN R01 APPLICATION

- Significance
- Investigators
 - Innovation
 - Approach
- Environment

Until 2024, each criterion was scored 1-9 (from highest to lowest), and reviewers also provided a total score which did not need to be an average of the five scores

SINCE 2024: SIMPLIFIED FRAMEWORK FOR PEER REVIEW

- 3 factors are scored. Only 2 get numerical scores (1-9) and one is basically yes/no. All three factors are considered in the **overall impact** score.
- **Factor 1: Importance of the Research** (Significance, Innovation)
- **Factor 2: Rigor and Feasibility** (Approach)
- **Factor 3: Expertise and Resources** (Investigator, Environment), to be evaluated as either
 - Appropriate
 - Needs additional expertise and/or resources (reviewer must address specific gaps in expertise or resources needed to carry out the project)

NIH EXPLANATION FOR THIS CHANGE

The reframing of the criteria serves to focus reviewers on three central questions reviewers should be evaluating:

- How **important** is the proposed research
- How **rigorous and feasible** are the methods
- Do the investigators and institution have the **expertise/resources** necessary to carry out the project.

MY THOUGHTS ON THIS CHANGE

- This change elevates significance and innovation a bit. Previously approach dominated the score. Thus the core ideas should now be more important than previously and are now more or less equal to the work that is being proposed.
- By downgrading investigator and environment into a yes/no option, and requiring specific comments on what is missing, it may help young investigators and diminish reliance on prior reputations.

SIGNIFICANCE

from NIH.gov/grants (2022)

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- 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.
- Explain how the proposed **project will improve** scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this **field will be changed** if the proposed aims are achieved.

SIGNIFICANCE

from NINDS website (2023)

Although you will emphasize your project's significance throughout the application, the Significance section should give the most details. 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.**

Reviewing the potentially relevant study section rosters may give you some ideas as to general reviewer expertise. **You will also need to describe the prior and preliminary studies that provide a strong scientific rationale for pursuing the proposed studies,** emphasizing the strengths and weaknesses in the **rigor** and transparency of these key studies.

HIGHLIGHTED ITEMS

The word **rigor** appears in both descriptions of significance.

This is a relatively new term in NIH applications and reflects an emphasis on the scientific quality of the work being presented.

REVIEWER GUIDANCE ON RIGOR AND TRANSPARENCY

- The full two-page document describing this criterion is applicable to all research and training grants since 2019.
- chrome-extension://efaidnbnmnnnibpcajpcgliclefi ndmkaj/https://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf

RIGOR AND TRANSPARENCY APPLIED TO SIGNIFICANCE

- As of 2019, all NIH applications have to address “**rigor and transparency**” in the application.
- These qualities must come through in both the SIGNIFICANCE and APPROACH sections.
- The SIGNIFICANCE section is where you address the rigor and transparency **of the prior research**.

TRANSPARENCY IN SIGNIFICANCE

- Transparency refers to “Consideration of Sex and Other Biological Variables”
- This includes the critical factors affecting health or disease in vertebrate animals or human subjects. Biological variables, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease.”
- You must consider the transparency of the papers you cite, including your own work

NIH LANGUAGE ON RIGOR IN SIGNIFICANCE

- Consider whether the prior research that serves as the key support for the proposed project is rigorous.
- Consider whether the investigators included plans to address weaknesses or gaps identified in the rigor of prior research.
- Weaknesses or gaps in the rigor of the prior research that serves as the key support for the proposed project, or the failure to address those weakness or gaps, may affect criterion and overall impact scores.

THE IMPORTANCE OF YOUR REVIEW OF THE LITERATURE TO SIGNIFICANCE

- SIGNIFICANCE is tightly linked to the literature review and background you must include in your application, even though there is no section called background or literature review
- My suggestion is that for your literature review to be valuable in SIGNIFICANCE, it must be a **targeted review**.

WHAT IS A TARGETED LITERATURE REVIEW?

- A literature review summarizes information on a subject.
- A targeted literature review summarizes information **to make a point**.
- The “target” is the overall goal of the review, which is to show why your research is needed
- This can be shown if you keep in mind several specific goals that should be achieved by your targeted literature review

5 GOALS OF THE TARGETED LITERATURE REVIEW

1. PUBLIC HEALTH: Convince the reviewers that the health problem you are addressing is indeed a cause of mortality, morbidity, cost. This addresses SIGNIFICANCE.
2. SCIENCE: Convince the reviewers that you have identified an interesting scientific issue. This partly addresses INNOVATION.
3. KNOWLEDGE: Convince the reviewers that you are well grounded in the science. This addresses INVESTIGATOR.
4. A SOLUTION: Convince the reader that you have a reasonable approach to solving the problem. This also addresses INNOVATION as well as APPROACH.
5. THE NEXT STEP: Most important of all: convince the reader that your work is the next key advance in the field. This addresses all criteria

USING THE LITERATURE REVIEW TO ESTABLISH YOUR RESEARCH NICHE

- Your review must be **thoroughly grounded** in the literature
 - You know **precisely** what others have done
 - You know that your approach is an **improvement, or move the field further forward**
- The better you know the literature, the more convincing you can be that your approach is an advance.
- In other words, you must identify the **research niche** your proposal occupies

FOUR LITERATURE REVIEW NO-NO'S

1. Do not **list** one study after another. Jones found this; Smith found that;
2. Do not elaborately **describe the methodology** of other people's studies, unless you are making a point about their methodology.
3. Do not review with the explicit purpose of **impressing** the reviewers. It never works.
4. Be very careful about **criticizing** other work. You do not know who knows who is on study section.

HOW TO REVIEW THE LITERATURE

- Remember that every citation is used for a single purpose – **to advance your argument**.
- Be sure, therefore, that the argument for which you are using the citation is **clear**.
- Be sure also that the **role of the citation** in your argument is clear. If the citation does not reinforce a point you are making, **omit it**.
- Be **concise**. No part of the proposal needs more effort in being concise than the literature review.

MORE ON HOW TO REVIEW THE LITERATURE

- Do not limit yourself to **new citations**. Medical research did not begin when Index Medicus went online. Some amazing science was done before that.
- Do not be **outdated** either. Use of very recent publications and presentations shows that you are on top of your field.
- Read the papers you cite **carefully**; a mis-citation of a published paper may cost you with reviewers
- Instead of criticizing other papers, point out how your study will **advance the science** over the studies thus far published.
- When resubmitting, **always update** your literature review from previous submission

USE TABLES AND FIGURES

- A **summary table** is a great way to convey information about studies succinctly. Summary tables save a lot of space!
- Focus the table on **measures of association**, not statistical significance. The size of the effect is what you want to convey.
- Figures can be used to illustrate **sharp changes** – time trends, for example, or dramatic differences.
- Don't use a figure unless the trends are **easily visible**.

ORGANIZATION OF REVIEW

- Often good to have a series of bullet points, each of which is illustrated by a few paragraphs, sometimes including tables and figures
- Good to end on a summary paragraph which **leads the literature directly to your study**, i.e. that the thrust of where the literature is heading is towards a study such as you are proposing. Thus your study **is the logical next step**.

MAIN PROBLEMS IN ENCOUNTERED IN TARGETED LITERATURE REVIEWS

- Failure to **know audience**, and therefore assuming knowledge. Risk overexplaining over under explaining.
- Failure to **argue logically**
- Failure to show **depth of knowledge** of the literature.
- Failure to **link** the literature to your study
- Failure to indicate how your study **resolves problems in the literature and advances the field**.