



**SOUND HEALTH
NETWORK**

Writing a Strong Research Plan

sound health initiative grant series

September 14, 2022

NATIONAL
ENDOWMENT for the **ARTS**

arts.gov





sound health initiative grant series

1. What You Need to Know to Apply for Music and Health Research Funding from the NEA and NIH (July 29, 2021) *video archived on [SoundHealth.ucsf.edu](https://www.soundhealth.ucsf.edu)
2. Writing a Strong Research Plan (TODAY)
3. Music and Health Grants Mock Study Section (Date TBD)





**SOUND HEALTH
NETWORK**

Mission

To promote research and public awareness about
the impact of music on health and wellness

SoundHealth.ucsf.edu

“Writing a Strong Research Plan”

Learning Objectives

- Become familiar with components of a Research Plan for a NIH music and health grant
- Understand the basic structure of a Specific Aims page
- Learn about the importance of significance, innovation, and conceptual models
- Acquire in-depth knowledge about the Research Design, Methods, and Data Analysis Plan sections

“Writing a Strong Research Plan” Workshop Outline

- Lineup for today’s workshop
- Overview of NIH and NEA music and health FOAs
- Introduction to the Research Plan section of a grant
- Specific Aims
- Significance and Innovation
- Approach & Data analysis
- Q & A (30 min)



Workshop *Notes*

- Close captioning is available.
- If you have questions for the panelists, please type them into the YouTube chat.
- We will answer as many questions as possible after the presentation.
- The video will be available immediately after the workshop at the same web address.



Lineup for today's workshop

- Julene Johnson, PhD (SHN co-director, UCSF Professor)
- Sheri Robb, PhD, MT-BC (SHN co-investigator, Indiana University Professor)
- Tor Neilands, PhD (UCSF Professor)
- Sunil Iyengar, NEA – Director, Office of Research & Analysis
- Tom Cheever, PhD NINDS – Program Director
- Abhi Subedi, PhD NINDS – Scientific Review Officer
- Luci Roberts, PhD NIA – Program Officer
- David Leitman, PhD NIMH – Program Officer
- Laura Thomas, PhD NIMH – Program Officer



Overview of NIH and NEA music and health FOAs



Tom Cheever, PhD
Program Director,
National Institute of
Neurological Disorders and Stroke (NINDS)



Sunil Iyengar
Research & Analysis Director,
Office of Research & Analysis
National Endowment for the Arts (NEA)

Overview of the Research Plan section of a grant

Specific Aims page*

Research Strategy

a. Significance

b. Innovation

c. Approach

Overview of the Research Plan section of a grant

Specific Aims page*

Research Strategy

a. Significance

b. Innovation

c. Approach

Human subjects and
clinical trial forms

Environment

Biosketches

Budget

Abstract

Caveat: There's not one way to write a grant.
Today, we're sharing our collective wisdom.



Overview of the Research Plan section of a grant

Specific Aims page*



Research Strategy

a. Significance

b. Innovation

c. Approach

The Specific Aims page

- is considered the most important page of your application
- is only ONE page (!)
- summarize the importance of the public health problem and gaps
- contain strong, compelling, and logical arguments for your research
- should be easy to read

SPECIFIC AIMS

Approximately 5.8 million adults age 60 and over in the United States (US) live with Alzheimer's disease and related dementias (AD/ADRD) at a cost of \$290 billion per year.¹ AD has a decades-long preclinical stage associated with progressive cognitive decline.² Older adults with mild cognitive impairment (MCI), an intermediate stage between typical aging and dementia,³ are 3-5 times more likely to progress to AD than those with normal cognition. Late-life engagement in cognitively challenging activities (e.g., playing a musical instrument, reading, learning a new language) is associated with decreased risk of cognitive decline.⁴⁻⁷ This is thought to occur by increasing cognitive and brain reserve and resilience in later life.^{8,9} In addition, addressing modifiable risk factors can slow the conversion from MCI to AD.¹⁰⁻¹²

Music training interventions^{13, 14} are a particularly promising strategy to address the modifiable risk factor of late-life cognitive inactivity. Music training can change brain structure and function in older adults, thereby leading to cognitive, perceptual, and psychosocial advantages. In several randomized trials, non-musician older adults who participate in music training (keyboard lessons) experienced improved executive function, cognitive control, attention, working memory, processing speed, verbal fluency and self-efficacy compared to controls.¹⁵⁻¹⁸ However, the mechanisms by which these music training interventions exert their effects are not yet understood. In addition, most of these keyboard studies used traditional piano training methods with music reading or other techniques focused on rote learning. Music training based on improvisation principles—the spontaneous generation of musical melodies and rhythms—will likely have more potent effects on cognition and brain function. Improvisation facilitates cognitive flexibility, self-monitoring, novel idea generation, execution of unplanned motor sequences and entrance into a state of “flow”.¹⁹ Biologically, improvisation is associated with distinct neural patterns involving activation of prefrontal networks that are linked to executive control, planning, learning and memory, in addition to deactivation of lateral prefrontal networks (involved in self-monitoring), among other brain networks.²⁰ As a mechanism of behavior change, it is likely that improvisation training will uniquely improve self-regulation (i.e., the ability to monitor and control one's own behavior, emotions, or thoughts and modify to situational demands).²¹ Self-regulation is a theoretically-relevant behavioral domain associated with long-term adherence to health behaviors.^{22,23} Yet, no research to date has tested whether music improvisation training can improve self-regulation and facilitate maintenance of cognitively challenging activities among older adults with and without MCI.

Here, we propose to develop and test the effects of a music improvisation training intervention on self-regulation among older adults with and without MCI. Our investigative team (Johnson, Limb and Bugos) has expertise in developing and testing music interventions for older adults, measuring brain mechanisms of improvisation, and studying cognitive outcomes. Our pilot data demonstrate improvements in executive function after traditional music training in older adults with MCI and brain imaging correlates of music improvisation in adults. Our overall hypothesis is that music improvisation training will lead to improvements in self-regulation, compared to controls, and that improvisation training will be associated with specific changes in prefrontal brain networks and ultimately cognitive engagement. The following specific aims will be completed:

Aim 1 (R61): Develop and refine a music improvisation training intervention that targets self-regulation and psychosocial well-being among older adults with and without MCI (NIH Stage 1a)

Aim 2 (R61): Evaluate feasibility & acceptability of the intervention and its effects on self-regulation via behavioral (Aim 2a) and neural (Aim 2b) assays among older adults with and without MCI (NIH Stage 1b)

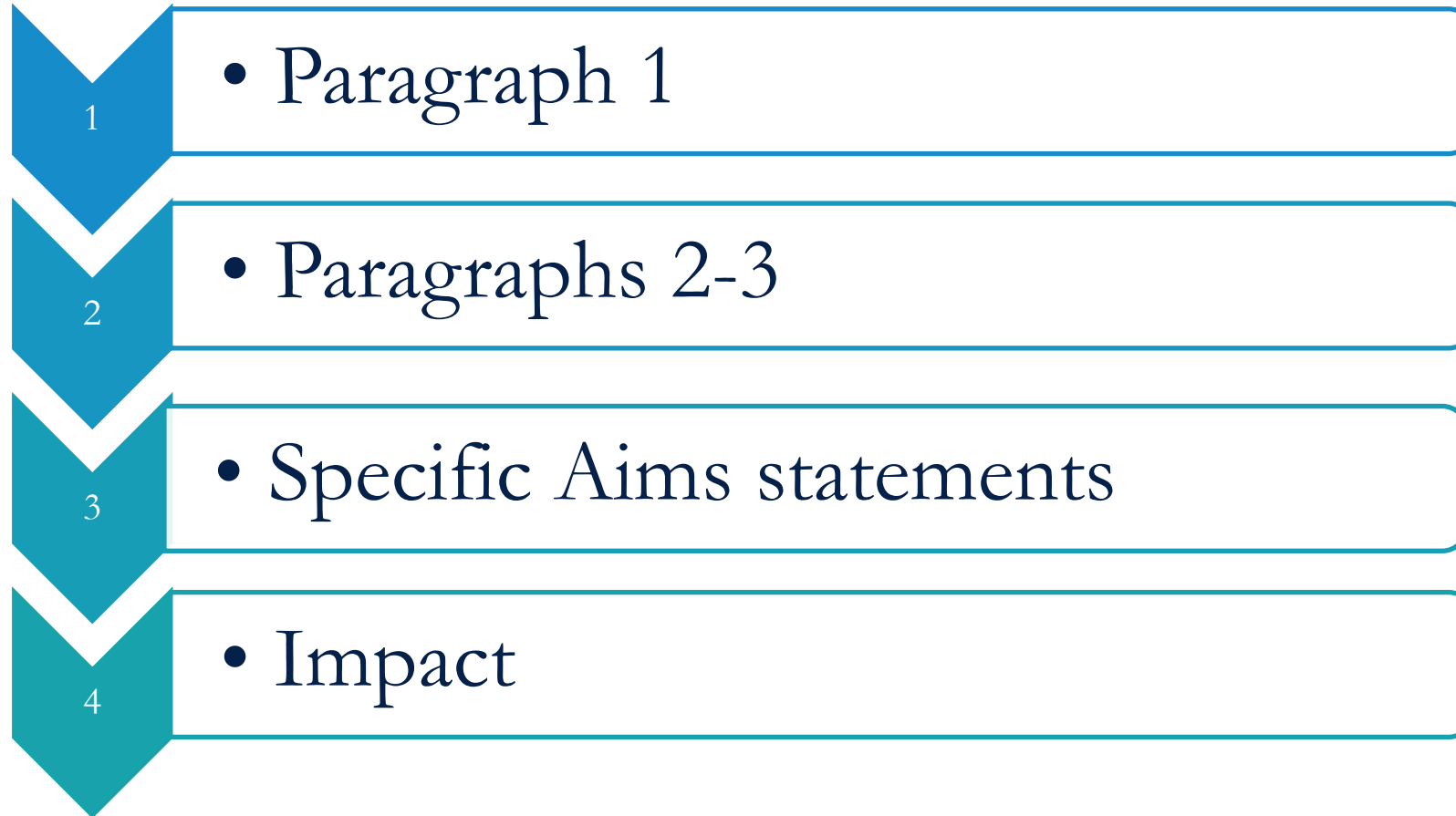
Go/No-Go Criteria: Go: (i) successful refinement of improvisation intervention for older adults with and without MCI; (ii) objective evidence of effect of improvisation training on self-regulation mechanism (via self-report and brain imaging assays); No-Go: (i) Unable to develop music improvisation intervention that has effects on self-regulation.

Aim 3 (R33): Conduct a randomized mechanistic trial to examine the effects of music improvisation intervention vs. attention control on self-regulation among adults with and without MCI (NIH Stage II)

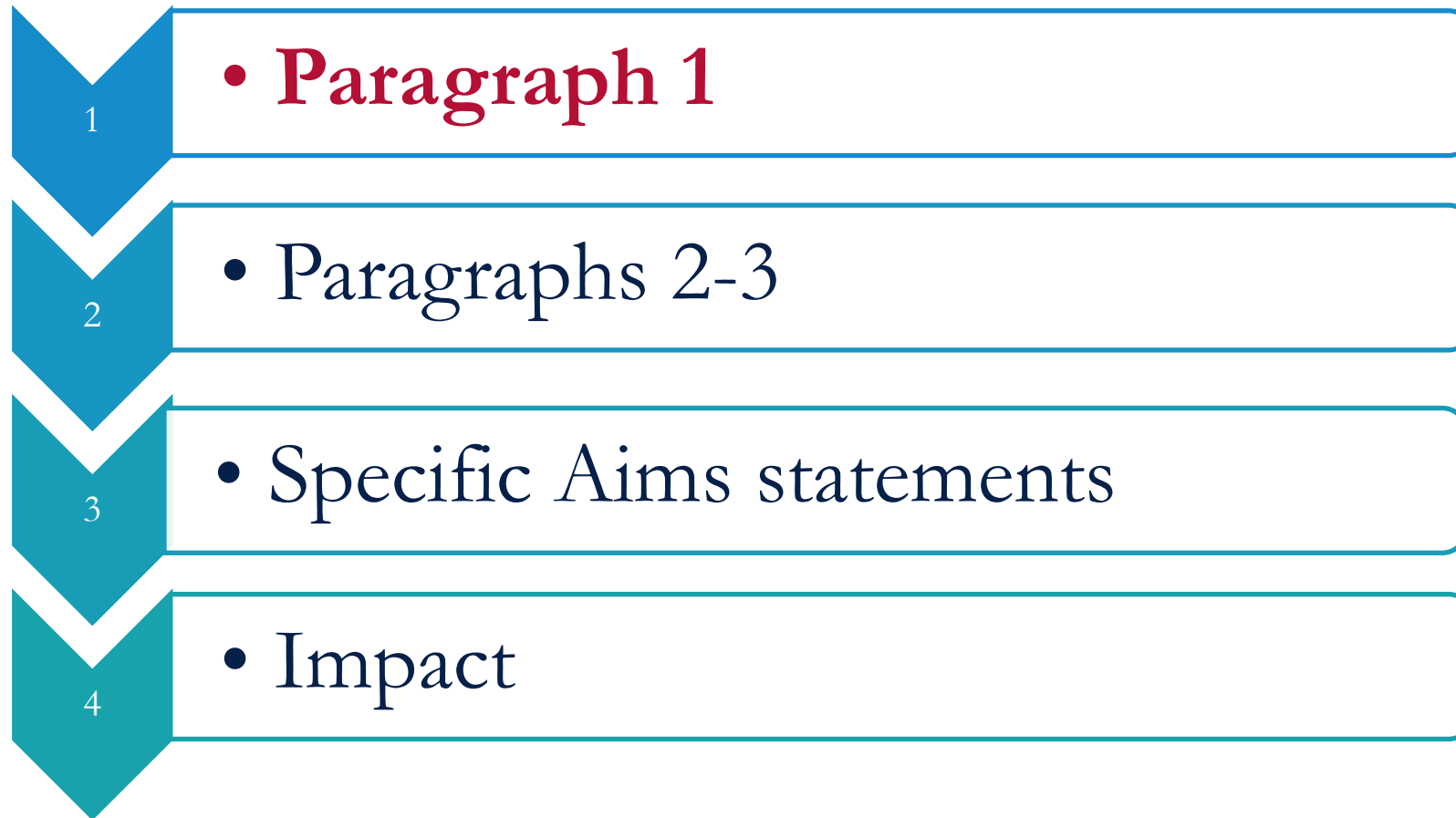
Hypothesis: Older adults who participate in the music improvisation intervention will experience significant improvements in self-regulation and psychosocial well-being, compared to controls.

IMPACT: If successful, findings from this study will improve our understanding of the mechanisms by which music improvisation training impacts self-regulation, as a key behavior change construct. If indicated, we will next conduct a principle-driven, multi-site randomized trial on the impact of music improvisation on self-regulation and sustained cognitive engagement among older adults with and without MCI (NIH Stage III or IV).

Specific Aims Building Blocks



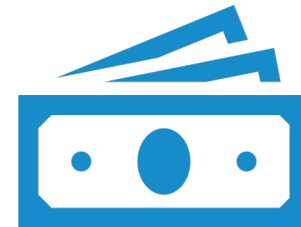
Specific Aims Building Blocks



Specific Aims: **Paragraph #1**



PURPOSE: provide a convincing argument of the importance of the public health problem



Importance of the problem

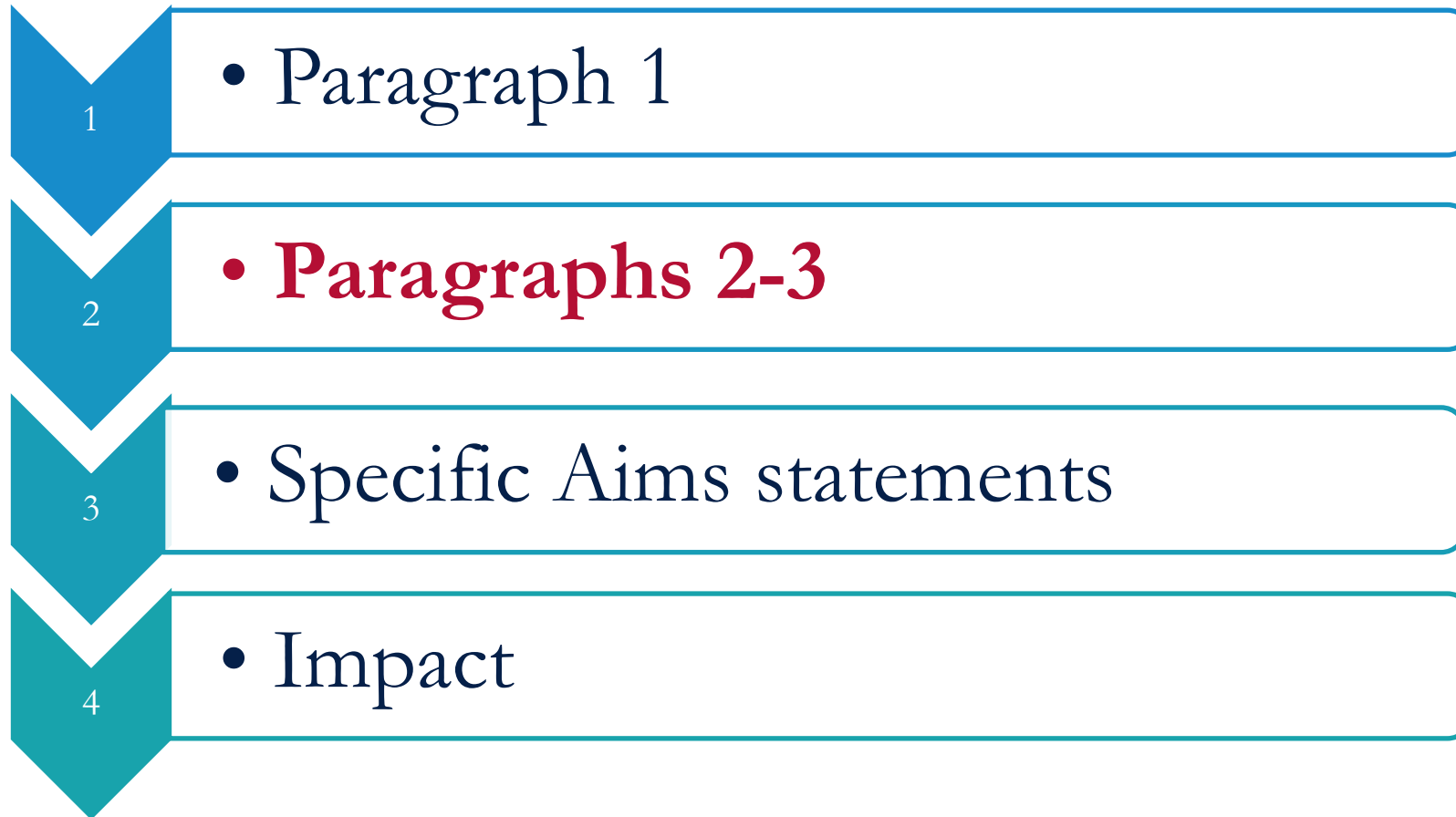
Affects a lot of people

Costs a lot of money (\$)

Has a negative impact on a variety of health outcomes

Other organizations (e.g., NIH, IOM) say that the problem is important

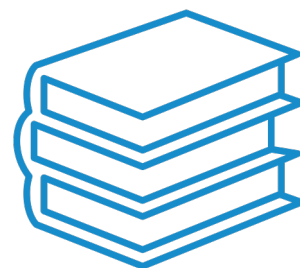
Specific Aims Building Blocks



Specific Aims: Paragraph #2



PURPOSE: to provide a convincing argument that your study is needed



Synthesize & critique existing literature in 5-6 sentences

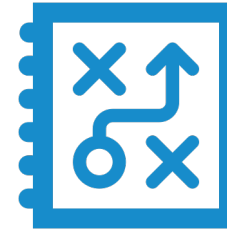
Identify the specific GAP that the grant will fill

State the facts - not broad generalizations

Specific Aims: **Paragraph #3**



PURPOSE: to provide a convincing argument that your grant will address the gap, provide a solution, and that YOU and your team should do the research



Purpose of your proposal

Overall hypothesis or research questions

Overall approach

Team expertise

Preliminary data, if appropriate

Specific Aims statements

- Therefore, the specific aims of this study are to...
- Start each aim with a verb
 - Aim 1: To [examine...]_____
 - Aim 2: To [determine...] _____
 - Aim 3: To [assess...] _____

- Each aim should provide the reviewer with an idea of the approach you will take to analyze your data
- Hypotheses and rationale can be included here too.



Ideally, the aims should be related, but not dependent, upon each other. The failure of one aim (or an unexpected result from one aim) should not negatively influence any other aim or prevent the completion of the other aims.

Overall Impact (*last paragraph of Specific Aims*)

- ~2-3 sentences
- Outlines the expected outcome
- Describes specific ways the proposed project will be of value to the funding agency, field of inquiry, and society.
- Addresses innovation and suggests the next study that builds on the proposed study

Specific Aims Building Blocks - summary

- 1 • Paragraph 1: importance of the public health problem
- 2 • Paragraphs 2: synthesis of literature and identify GAP
- 3 • Paragraph 3: why YOU and your TEAM should do the study
- 4 • Aims statements
- Impact: expected outcome and effect on science / field

Thoughts on the Style of a Specific Aims page

- Includes strong logical arguments
- Provides specific information
 - Example: “50 million Americans report chronic pain” / rather than “chronic pain is a problem”
- Uses short, discrete, easy-to-read sentences
 - every word matters
 - make sure the sentences are clear and crisp / “punchy”
 - avoid situations where your reviewer might “trip” on a word or sentence
 - avoid long sentences, especially with dependent clauses
- Uses consistent terminology & abbreviations
 - Define conditions and terms, if needed (not all reviewers will be experts in your area)

Research Strategy

- Significance
- Innovation
- Approach



Significance and Innovation

Sheri Robb, PhD, MT-BC
Indiana University School of Nursing
Indiana Clinical & Translational
Sciences Institute

Significance Section



Establish the **PROBLEM** or critical barrier to progress in the field.



Establish the gap in the literature / establish the **NEED** for this work.



Discuss the **SCIENTIFIC RIGOR** – strengths and weaknesses of prior literature supporting your project.



Significance of expected research **CONTRIBUTION** - how/why findings will have an important and positive impact.

Significance: Scored Review Criteria

Does the project address an **important problem or a critical barrier** to progress in the field?

Is prior research supporting the proposed project **rigorous**?

If the proposed aims are achieved, how will **scientific knowledge or clinical practice improve**?

How will successful completion of the aims **change** the concepts, methods, technologies, treatments, services, or preventative interventions that **drive the field**?

Look at the Funding Opportunity Announcement (FOA) for specific review criteria.

Significance: Structuring the Entry



Establish the **PROBLEM** or critical barrier to progress in the field.



Establish the gap in the literature / establish the **NEED** for this work.



Discuss the **SCIENTIFIC RIGOR** – strengths and weaknesses of prior literature supporting your project.



Significance of expected research **CONTRIBUTION** - how/why findings will have an important and positive impact.

Significance Section Example

A.1. This study addresses major gaps in our understanding about how music interventions affect biological function.

A.2. This study addresses the absence of theoretically based music interventions and rigorous mechanistic trials examining the biobehavioral effects and dose response of music.

A.3. This study addresses the important clinical problem of cancer-related stress and its impact on the interrelated emotional well-being of young children and parents during cancer treatment.

A.4. Within the context of pediatric cancer treatment, there are special challenges to overcome to measure cortisol and immune function.

Potential Impact. As the first pediatric music intervention study to examine biomarkers of stress and immune function, findings will inform clinical practice in important ways...



Establish Problem or Critical Barrier



Establish Gaps in the Literature/Need for Work

A.1. This study addresses **major gaps in our understanding about how music interventions affect biological function.**

-Review of literature

-Establish what is known/not known

-Establish why this is a barrier; importance of addressing it

-How the proposed study will address the identified gap

A.3. This study addresses the **important clinical problem of cancer-related stress and its impact on the interrelated emotional well-being of young children and parents during cancer treatment.**

-Affects a lot of people, poor outcomes, lack of treatments, costly...

-What is known/not known

-How the proposed aims will address the problem



Discuss Scientific Rigor

A.2. This study addresses the absence of theoretically based music interventions and rigorous mechanistic trials examining the biobehavioral effects and dose response of music.

“Rigorous research examining the use of music for health must consider the etiology of the clinical problem under investigation and provide a clear scientific premise for how and why the specified use of music is expected to influence the outcome of interest.”

- Discuss scientific rigor of studies to date (related to your aims)
- Identify strengths and weaknesses of relevant literature and preliminary data
- Discuss how study will address weakness and improve rigor
- Build scientific rationale (premise) for the proposed aims

A.4. Within the context of pediatric cancer treatment, there are special challenges to overcome to measure cortisol and immune function.

- Plan to overcome identified methodological challenges & ensure rigor
- Building rationale for aims and methodological approach

Rigor and Reproducibility: Four Focus Areas

Enhancing Reproducibility in NIH Applications: Resource Chart

NIH Grants Policy Website: <http://grants.nih.gov/reproducibility/index.htm>

NIH Website: <https://www.nih.gov/research-training/governance/reproducibility>

4 AREAS OF FOCUS	WHAT DOES IT MEAN?	WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?
Rigor of the Prior Research	<p>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.</p> <p>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.</p> <p>Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.</p> <p><i>*See related FAQs, blog post</i></p>	<p>Research Strategy</p> <ul style="list-style-type: none"> ➤ Significance ➤ Approach
Scientific Rigor (Design)	<p>Scientific rigor is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results.</p> <p>Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.</p> <p><i>*See related FAQs, blog post, examples from pilots</i></p>	<p>Research Strategy</p> <ul style="list-style-type: none"> ➤ Approach
Biological Variables	<p>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.</p> <p>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.</p> <p><i>*See related FAQs, blog posts, article</i></p>	<p>Research Strategy</p> <ul style="list-style-type: none"> ➤ Approach
Authentication	<p>Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics.</p> <p>Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not have been generated with NIH funds and:</p> <ul style="list-style-type: none"> • may differ from laboratory to laboratory or over time; • may have qualities and/or qualifications that could influence the research data; • are integral to the proposed research. <p>The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan.</p> <p><i>*See related FAQs, blog post, examples</i></p>	<p>Other Research Plan Section</p> <ul style="list-style-type: none"> ➤ Include as an attachment ➤ Do not include in the Research Strategy.

****This chart is based on general instructions for research grant applications submitted for January 25, 2019 due dates and beyond. It should only be used as a guide. For all applications, please read the applicable Funding Opportunity Announcement (FOA) & Application Guide for specific instructions.**

Enhancing Reproducibility in NIH Applications: Resource Chart
<https://grants.nih.gov/policy/reproducibility/guidance.htm>

Rigor and Reproducibility

4 AREAS OF FOCUS	WHAT DOES IT MEAN?	WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?
<p>Rigor of the Prior Research</p>	<p>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.</p> <p>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.</p> <p>Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project</p>	<p>Research Strategy</p> <ul style="list-style-type: none"> ➤ Significance ➤ Approach



Significance of Expected Contribution

How & why findings will have an important impact.

- **One paragraph statement of the expected contribution when proposed aims are complete.**

***Potential Impact.** As the first pediatric music intervention study to examine biomarkers of stress and immune function, findings will inform clinical practice in three important ways.*

- **Explain how the contribution is likely to improve scientific knowledge, technical capability, or clinical practice (review criteria).**

First, findings will increase our understanding about how active music effects parent and child stress (and the interrelated nature of their stress) at the biological level; confirming or disconfirming use of a dyadic approach. Second, ----- Finally, -----.

- **Conclude with statement of overall contribution.**

Coupled with findings from our current R01, we are uniquely positioned to isolate attributes of the intervention that are most likely responsible for observed outcomes allowing us to optimize the intervention and examine its efficacy in a broader population of children with acute/chronic illness and their parents.

Innovation Section



Significance Section centers on the **PROBLEM** or critical barrier



Innovation Section centers on the **SOLUTIONS** you bring that represent a new approach to solving that problem.

Innovation: Scored Review Criteria

Does this application challenge and seek to shift current research or clinical practice paradigms by using **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 a **refinement, improvement, or new application** of theoretical concepts, approaches or methodologies, instrumentation or interventions **proposed?**

Look at the Funding Opportunity Announcement (FOA) for specific review criteria.

Innovation Section Example

B.1. This is the first biological examination of an active music engagement intervention to reduce stress and improve related immunosuppression during pediatric cancer treatment.

B.2. The use of music to address interrelated child-parent distress during cancer treatment is innovative.

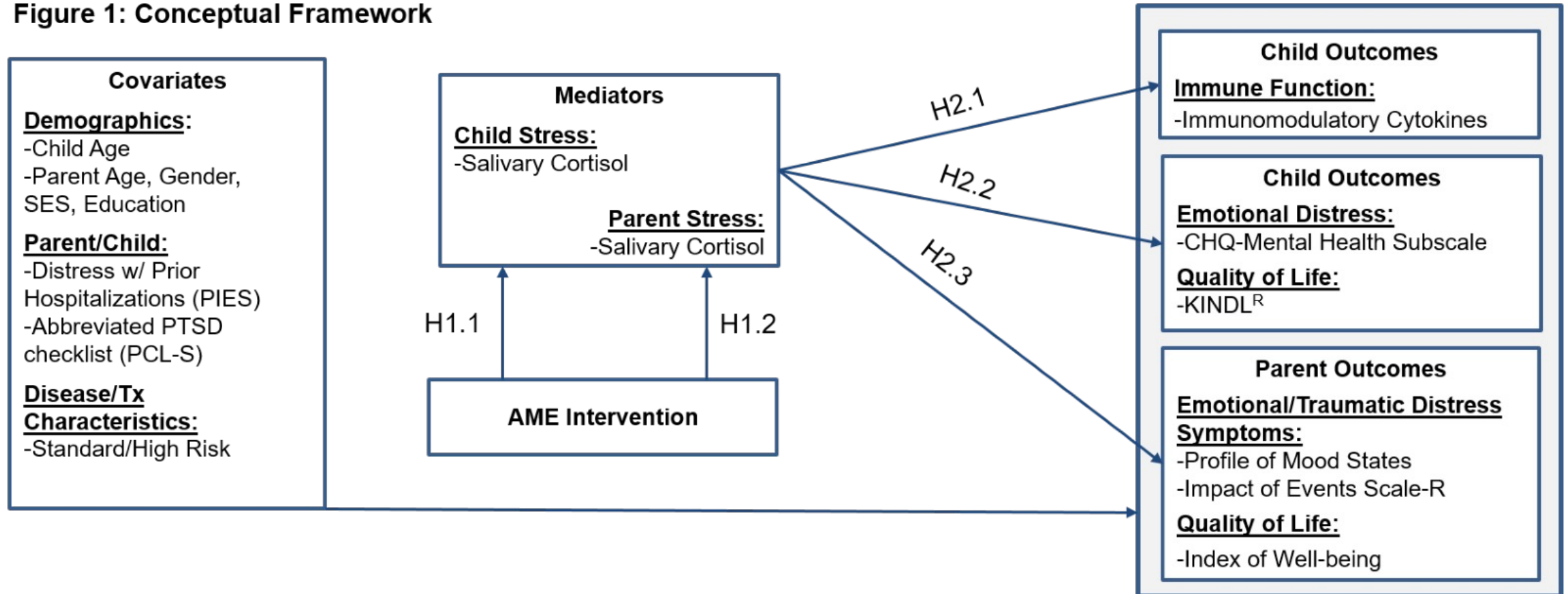
B.3. Our team is uniquely positioned to shift current research and clinical practice paradigms by merging findings from the proposed study with findings from our current R01 to create a biobehavioral framework for music interventions.

Conceptual Framework

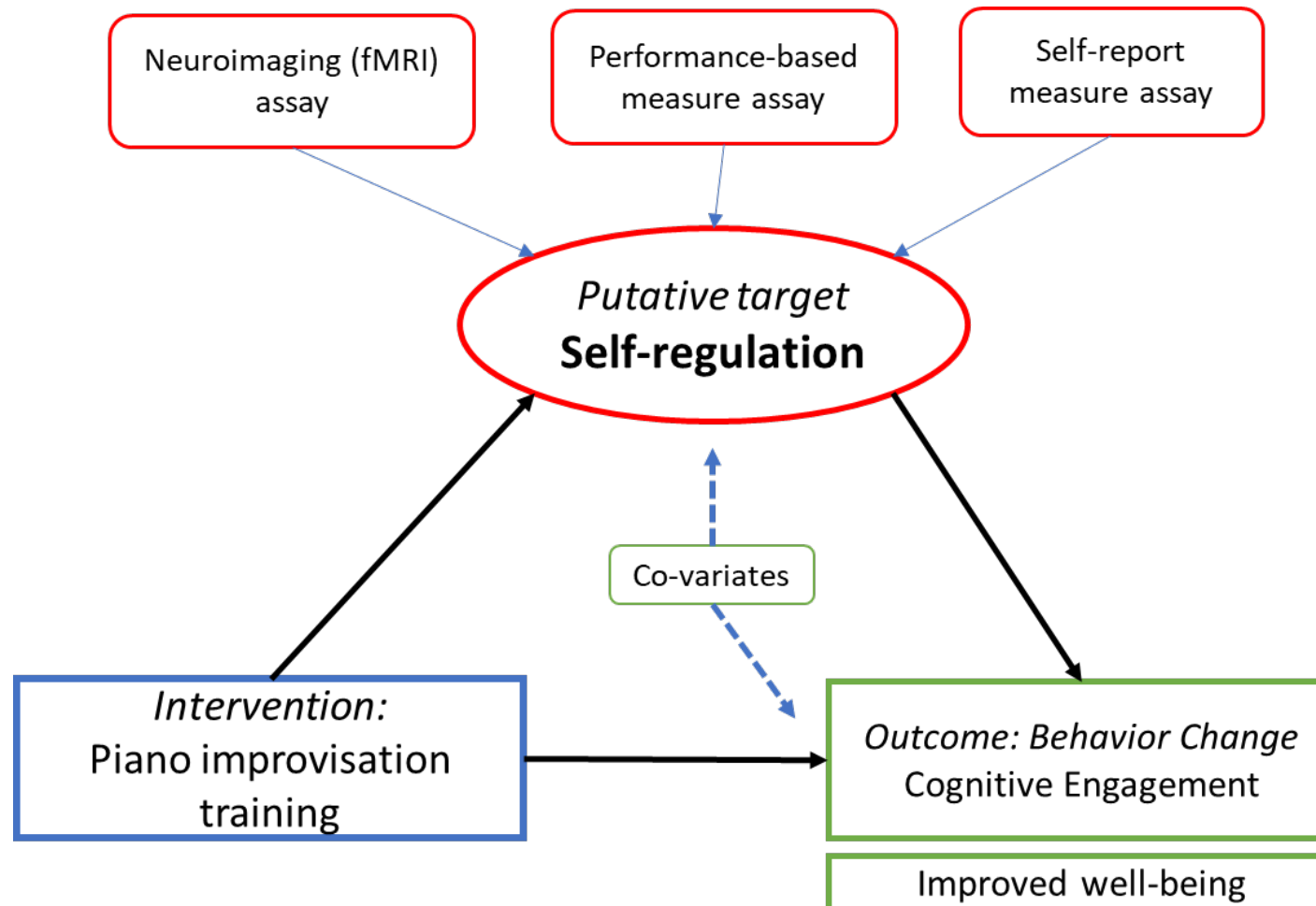
- Provides a visual depiction of the proposed study, specific aims, and hypotheses.
- Ties together theory and scientific evidence that informed study aims and variables of interest.
- Recommend including both a figure and narrative.
- Locate at front of Approach Section or end of Significance/Innovation.

Conceptual Framework Example

Figure 1: Conceptual Framework



Conceptual Framework Example



Self-regulation is defined as “the ability to monitor and control our own behavior, emotions, or thoughts, altering them in accordance with the demands of the situation”

Research Strategy

- *Significance*
- *Innovation*

- Approach



5-minute Break



Research Strategy

- *Significance*
- *Innovation*

- Approach





Approach and Data Analysis

Tor Neilands, PhD

Analysis Core
Center for Aging in Diverse
Communities (CADC)

University of California,
San Francisco



Overview of Approach Section

- The approach section is often the section that scores poorest and receives the most reviewer comments in NIH reviews.
- Thus, the overall goal of my presentation is to invite you to consider how you can make your approach sections as rigorous as possible by:
 - Describing the approach section of an NIH grant application and its' core components.
 - Offering some recommendations for developing a strong and rigorous approach section.
 - Describing some cautions offered by NIH on what can cause approach sections to be scored poorly.

Study Team

- Many applicants like to include a paragraph describing the study team.
 - Note: the music and health FOAs encourage interdisciplinary teams
- List the PI first with 2-4 sentences describing their expertise and previous experience qualifying them to conduct this study.
- Each co-investigator and consultant could have 1-2 sentences listing their expertise and what they bring to the study.
- Conclude the paragraph with a sentence referring reviewers to the investigators' biosketches for more about their qualifications and to the personnel section of the budget justification to learn more about their anticipated contributions to the proposed study.
- Including this type of paragraph is more difficult in 6-page applications (e.g., R21) than in 12-page applications (e.g., R01). On the other hand, mechanisms with fewer pages often support smaller teams, which increases the feasibility of including a very short paragraph describing the research team.

Preliminary Studies: Include?

- Stated: Some NIH grant applications are expected to report on preliminary studies or data (e.g., R01) whereas others typically are not (e.g., R61/33, R21).
- Unstated: Norms may vary by field and NIH study section, so it is a good idea to check with mentors, colleagues, and NIH program officials about whether preliminary data are required for the NIH grant mechanism to which you are applying.

Preliminary Studies: What to include?

- Summaries of your published and unpublished (pre-publication) findings that support the scientific premise of your study.
- Descriptions of your ability to feasibly and acceptably (to the study population) recruit participants and collect primary data (if you are proposing to collect primary data) or skills and team to extract and analyze secondary data if you are proposing secondary data analyses.
 - Example: Reporting on strong retention rates from prior longitudinal work conducted by you and your team if you are proposing a longitudinal study.
- Lead with your work but don't forget to include relevant work produced by your collaborators, even if you weren't directly involved in it.
- Include penultimate summarizing sentences followed by a final gap sentence per paragraph to point out the need for the current study.

Research Design and Methods

- Once you have elucidated the gaps needing study via a conceptual framework diagram, you are ready to articulate the research design and methods.
- A popular strategy is to lay these out aim-by-aim in sequential order.
- Within each aim, you would describe:
 - The study design (e.g., randomized controlled waitlist trial, cluster-randomized trial, observational cohort, mixed method QUAL->quant, etc.)
 - Data collection setting (for studies proposing to collect primary data).
 - The population you are planning to study.
 - The sample you plan to collect and how you will recruit research participants.
 - Measures (often listed in a table).
 - Data Analysis Plan and sample size justification
 - Summary of what will be learned from the aim's activities, and, if applicable, how those will inform the next aim, but without aim dependence.

Data Analysis and Sample Size Plan

- Outlines and order of presentation of considerations will vary by grant mechanism and scientific content. Here is an example:
 - Descriptive statistics and missing data
 - Primary inferential analyses
 - Hypotheses
 - Models and estimation approaches used to test primary hypotheses
 - Secondary/exploratory inferential analyses
 - Sample size justification (power analysis) narrative paragraph and, if applicable, supporting tables of power or minimum detectable effects
- NIH-defined clinical trials: Do not forget to supply a more detailed analysis and sample size justification to appear in human subjects section Forms-G. You may include a more abbreviated version in the research strategy with cross-referencing to Forms-G.

Sex as a Biological Variable

- Women have been underrepresented in federally-funded research.
- To address this disparity, NIH instituted a policy in 2016 regarding sex as a biological variable.
- “NIH expects that sex as a biological variable will be 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. Investigators are strongly encouraged to discuss these issues with NIH program staff prior to submission of applications.” (<https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>). Implications:
 - Include justification for distribution of the biological sex of participants in the sampling subsection of the approach
 - Include language in the data analysis plan describing analyses that take biological sex into account (e.g., sex-stratified analyses, interaction terms involving biological sex).
- For further details, see <https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>.

Data Sharing Plan

- Effective January 25, 2023, NIH will require investigators applying for NIH funding to submit a two-page detailed data sharing plan. This plan is separate from the research strategy document (i.e., it does not count against the research strategy page limits).
- The outline of the plan should include the data type; related tools, software, and code; standards; data preservation, access, and associated timelines; access, distribution, and reuse considerations; and oversight of data management and sharing. See <https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-DMS/writing-a-data-management-and-sharing-plan> for definitions of each of these categories.
- See Data Management and Sharing Plans paragraph of <https://www.nimh.nih.gov/funding/managing-your-grant/nimh-data-sharing-for-applicants-and-awardees> for examples.

Final Paragraphs

- Penultimate paragraph: Anticipated concerns and alternative strategies
 - List potential problems and how you might overcome them. In my experience, this section often focuses on issues involving difficulties recruiting participants rather than other issues, such as data analysis challenges.
- Final paragraph: Summary of anticipated contributions
 - This paragraph is an opportunity for you to summarize what you anticipate will be the high health impact of your proposed study.
 - Written compellingly, it will have NIH reviewers leaving your application on a high note.

Top 10 Problems in NIH Applications

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- **Questionable reasoning in experimental approach**
- **Uncritical approach**
- **Diffuse, superficial, or unfocused research plan**
- **Lack of sufficient experimental detail**
- Lack of knowledge of published relevant work
- **Unrealistically large amount of work proposed**
- **Uncertainty concerning future directions**

According to

<https://nexus.od.nih.gov/all/2022/04/01/top-10-problems-reviewers-cite-in-applications/>:



Problems with the Approach

- Too much unnecessary experimental detail
- Not enough detail on approaches, especially untested ones
- Not enough preliminary data to establish feasibility
- Feasibility of each aim not shown
- Little or no expertise with approach
- Lack of appropriate controls
- Not directly testing hypothesis
- Correlative or descriptive data
- Inadequate consideration of power
- Experiments not directed towards mechanisms
- No discussion of alternative models or hypotheses
- No discussion of potential pitfalls
- No discussion of interpretation of data

According to <https://www.nimh.nih.gov/funding/grant-writing-and-application-process/common-mistakes-in-writing-applications>

Tor's Final Thoughts

- The approach can be the hardest section of the research strategy to write because it can differ substantially from one application to another depending on the scientific requirements of the application – one size doesn't fit all. For learners by example, that can make mastering writing an approach section especially challenging.
- As always, I recommend:
 - Starting the drafting process as early as possible.
 - Seeking intramural review from colleagues and mentors iteratively and often. Review others' applications, too.
 - Try to anticipate reviewer questions and get ahead of them in the application.

Additional Resources

- NIH Grant Application Basics (Includes guides, tips, and tutorials) http://grants.nih.gov/grants/grant_basics.htm
- Information on Study Sections <http://cms.csr.nih.gov/>
- Enhancing Reproducibility in NIH Applications: Resource Chart <https://grants.nih.gov/grants/Rigor-and-Reproducibility-Chart-508.pdf>
- All About Grants podcast: <https://grants.nih.gov/news/virtual-learning/podcasts.htm>
- NIH Grants YouTube Channel: <https://www.youtube.com/user/nihgrants>
- NIAID Sample Grant Applications and Summary Statements: <https://www.niaid.nih.gov/grants-contracts/apply-grant>

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Q & A



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