Research Strategy-2: Approach

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For Research grants, *Approach* is assessed as Factor 2: Rigor & Feasibility


Significance


Innovation

Factor 1 (scored 1–9)
Importance of the Research


Approach

Factor 2 (scored 1–9)
Rigor & Feasibility


Investigators


Environment

Factor 3 (overall impact)
Expertise & Resources

https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review/framework

For K awards, *Approach* is assessed as part of the Research Plan


Candidate


Career Development Plan


Research Plan


Mentors


Environment & Institutional Commitment

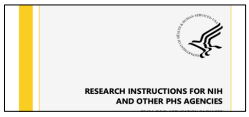
→ Significance
→ Innovation
→ ***Approach***

The space for the Approach section depends on the grant mechanism

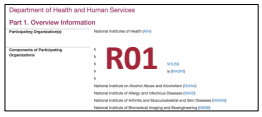
Section		R01	R03/R21	K08/K23
Research Strategy	Significance	1½ page	2/3 page	2/3 page
	Innovation	½ page	1/3 page	1/3 page
	Approach	**10 pages**	**5 pages**	**~6 pages***
	Total	12 pages	6 pages	~7 pages*

*K Awards have a total of 12 pages for the Career Development Plan and the Research Plan: devoting ~5 pages to the Career Plan and 1 page to Significance & Innovation leaves ~7 pages for the Approach

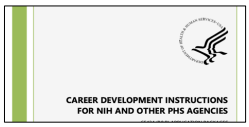
Follow the appropriate NIH Instructions and the Program Announcement for specific details



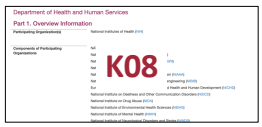
Research Instructions:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf



PA-25-301:
https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html



Career Development Awards:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/career-forms-i.pdf



PA-24-182:
https://grants.nih.gov/grants/guide/pa-files/PA-24-182.html

Overall strategy for the approach section . . . .

Provide sufficient information to convince your reviewers that ***you are ready*** to conduct the proposed research project upon receipt of the award – and that you are ***prepared to successfully complete*** the proposed research plan.

Follow NIH guidelines for this section (R & K awards)

- Describe the overall **strategy, methods, and analyses** to be used to accomplish the specific aims of the project
- Describe plans to address **weaknesses in the rigor of the prior research** that serves as the key support for the proposed project
- Describe the **experimental design and methods** proposed and how they will achieve robust and unbiased results
- Describe how the data will be **collected, analyzed, interpreted**

Research Instructions:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf

Career Development Awards:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/career-forms-i.pdf

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Follow NIH guidelines for this section (R & K awards)

- Discuss potential **problems, pitfalls, limitation and alternative approaches**
- For trials that randomize groups or deliver interventions to groups, describe how your **methods for analysis and sample size** are appropriate
- If the project is in the early stages of development, describe any strategy to establish **feasibility**, and address the management of any **high risk aspects** of the proposed work

Research Instructions: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf

Career Development Awards: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/career-forms-i.pdf

For K Awards, NIH requires the following for the Approach section

- A sound research project that is consistent with the candidate's level of research development and objectives of their career development plan must be provided. The research description should demonstrate the quality of the candidate's research thus far and also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's research and the candidate's proposed research plan.

PA-24-182: https://grants.nih.gov/grants/guide/pa-files/PA-24-182.html

NIH asks reviewers to consider these questions for the Research Plan in a K Award

- Are the proposed research questions, design, and methodology of **significant scientific and technical merit**?
- Is the **prior research** that serves as the key support for the proposed project **rigorous**?
- Has the candidate included plans to **address weaknesses in the rigor of prior research** that serves as the key support for the proposed project?
- Has the candidate presented strategies to ensure a **robust and unbiased approach**, as appropriate for the work proposed?

PA-24-182: https://grants.nih.gov/grants/guide/pa-files/PA-24-182.html

NIH asks reviewers to consider these questions for the Research Plan in a K Award

- Has the candidate presented adequate plans to address **relevant biological variables**, such as sex, for studies in vertebrate animals or human subjects?
- Is the research plan **relevant to the candidate's** research career objectives?
- Is the research plan **appropriate to the candidate's stage** of research development and as a vehicle for developing the research skills described in the career development plan?

Use as a checklist when drafting your aims!

PA-24-182: https://grants.nih.gov/grants/guide/pa-files/PA-24-182.html

NIH asks reviewers to consider these questions for Factor 2 (Rigor & Feasibility) for Research Awards

Overall Approach

- Evaluate the scientific quality of the proposed work
- Evaluate the likelihood that compelling, reproducible findings will result (**rigor**)
- Assess whether the proposed studies can be done well and within the timeframes proposed (**feasibility**)

PA-25-301: https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html

NIH asks reviewers to consider these questions for Factor 2 (Rigor & Feasibility) for Research Awards

Rigor

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.

PA-25-301: https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html

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NIH asks reviewers to consider these questions for Factor 2 (Rigor & Feasibility) for Research Awards

Rigor

- Evaluate whether the investigators presented adequate plans to address relevant **biological variables**
- For applications involving **human subjects or vertebrate animals**, also evaluate:
  - the rigor of the intervention or study manipulation
  - whether outcome variables are justified.
  - whether the results will be generalizable
  - whether the sample is appropriate and sufficiently diverse to address the proposed question(s)

PA-25-301: https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html

NIH asks reviewers to consider these questions for Factor 2 (Rigor & Feasibility) for Research Awards

Feasibility

- Evaluate whether the proposed approach is **sound and achievable**, including plans to address problems or new challenges that emerge in the work
- For applications involving **human subjects**, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain a study population that appropriately models the target population
- For **clinical trial applications**, evaluate whether the study timeline and milestones are feasible

PA-25-301: https://grants.nih.gov/grants/guide/pa-files/PA-25-301.html

You must also address other concerns in the Approach section

- Explain how **relevant biological variables**, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans
- Point out any procedures, situations, or materials that may be **hazardous** to personnel and the precautions to be exercised
- Justify use of **Human Embryonic Stem Cells** (hESCs)
- Justify use of **human fetal tissue** obtained from elective abortions (HFT)

Research Instructions:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf

Career Development Awards:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/career-forms-i.pdf

A "Modular" approach is one strategy for the Research Plan

For each Aim:

- Introduction
- Background
- Preliminary results
- Research design
- Expected outcomes
- Potential problems, pitfalls and alternative approaches

Entire Proposal:

- Scientific Rigor
- Timeline
- Future Directions

Alternatively, use a "Unitary" Approach

- Introduction
- Background
- Preliminary Studies
- **Research Design**
  - Rationale for study design
  - Study population
  - Study methods and procedures
  - Study measurements
  - Data collection, quality and management
  - Data analysis including plans for statistical analysis
  - Expected outcomes
  - Potential problems, pitfalls and alternative approaches
  - Timeline
  - Future Directions

For each Aim . . .

Use a descriptive, outcome-based title from your specific aims

First paragraph:

- State the objectives of the aim
- Describe how this aim fits with the overall research strategy
- Briefly outline experimental approach

The reviewer should quickly understand the rationale of each aim

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Provide sufficient experimental detail to allow the reviewer to evaluate feasibility & outcomes

- be guided by how well a method is described in the literature
  - — common techniques just need a reference
  - — less common methods require more detail
  - — describe modifications to standard techniques
- if the project is in the early stages of development, describe any strategy to establish feasibility
  - preliminary data
  - previous experience (published?)
  - use of mentors &/or collaborators

Discuss potential problems, alternative strategies & benchmarks for success

Most Important!

— *shows the reviewer that you have thought through your experiments*

- what might not work?
- what alternative approach would you use?
  - — Plan B, Plan C, etc.
  - — who can help?
- define for the reviewer how you will know that you have achieved the expected outcomes?
  - — predictions from hypothesis

Provide a timeline for your research strategy

- Fit the aims to the effort and project timeline
- Avoid contingent aims (the "fatal flaw")

Provide a timeline for your aims in the proposal

Aim	Year 1	Year 2	Year 3
1	→		
2		→	
3			→

A timeline shows the reviewers you are ready to conduct the proposed research because you have "walked" yourself through every aspect of the project

Note any requirements related to compliance

Relevant Biological Variables (e.g., sex)
- how are these factored into research design
- strong justification is required for projects using only one sex

Hazardous Materials or Procedures
- describe & list precautions

Human Embryonic Stem Cells
- justify using a cell line not on the NIH hESC Registry

Looks Do Matter — Edit and Polish your proposal

- Make your proposal easy to read by including **WHITE SPACE** between every paragraph
- Nothing puts a reviewer to sleep faster than text that is **TOO DENSE**
- Use the **KISS Principle** – keep it short and simple
- Communicate the **OUTCOMES** of your research project and how this will improve knowledge and/or health care practice

Follow advice from NIH . . .

Remember to include:

- While describing a method in the Approach section, state your and/or your collaborators' experience with it.
- Point out that you have access to a necessary piece of equipment.
- When explaining your field and the status of current research, weave in your own work and any preliminary data.
- Delve into the biology of the area to make sure reviewers will grasp the importance of your research, understand your field, and how the proposed work fits into it.

https://www.niaid.nih.gov/grants-contracts/write-research-plan#A8

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Be your own reviewer . . .

- Will the investigators be able to get the work done within the project period, or is the proposed work over ambitious?
- Did the PI describe potential pitfalls and possible alternatives?
- Will the experiments generate meaningful data?
- Could the resulting data support the hypothesis?
- Are others already doing the work, or has it been already completed?

https://www.niaid.nih.gov/grants-contracts/write-research-plan#A8

Make use of graphics and tables — they can be worth a thousand words

- Make sure font size is appropriate and figures and graphs aren't misleading.
- Remember to label figures and tables



Tips for a successful approach section

Step 1: Start with Specific Aims as a roadmap

Step 2: Create an outline

Step 3: Decide on figures and tables

Step 4: Write the first draft

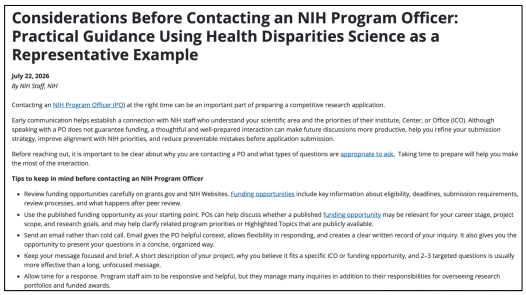
Step 5: Check that what you have written matches your Specific Aims

Step 6: Edit sections to meet submission guidelines for proposal length

Step 7: Spell check and polish

Step 8: Get feedback!!

Talk to your Program Officer



Considerations Before Contacting an NIH Program Officer: Practical Guidance Using Health Disparities Science as a Representative Example

July 22, 2026
By NIH Staff, NIH

Contacting an NIH Program Officer (PO) at the right time can be an important part of preparing a competitive research application.

Early communication helps establish a connection with NIH staff who understand your scientific area and the priorities of their Institute, Center, or Office (ICO). Although speaking with a PO does not guarantee funding, a thoughtful and well-prepared interaction can make future discussions more productive, help you refine your submission strategy, improve alignment with NIH priorities, and reduce preventable mistakes before application submission.

Before reaching out, it is important to be clear about why you are contacting a PO and what types of questions are appropriate to ask. Taking time to prepare will help you make the most of the interaction.

Tips to keep in mind before contacting an NIH Program Officer

- Review funding opportunities carefully on grants.gov and NIH Websites. Funding opportunities include key information about eligibility, deadlines, submission requirements, review processes, and what happens after peer review.
- Use the published funding opportunity as your starting point. POs can help discuss whether a published funding opportunity may be relevant for your career stage, project scope, and research goals, and may help clarify related program priorities or Highlighted Topics that are publicly available.
- Send an email rather than cold call. Email gives the PO helpful context, allows flexibility in responding, and creates a clear written record of your inquiry. It also gives you the opportunity to present your questions in a concise, organized way.
- Keep your message focused and brief. A short description of your project, why you believe it fits a specific ICO or funding opportunity, and 2–3 targeted questions is usually more effective than a long, unfocused message.
- Allow time for a response. Program staff aim to be responsive and helpful, but they manage many inquiries in addition to their responsibilities for overseeing research portfolios and funded awards.

https://grants.nih.gov/news-events/nih-extramural-nexus-news/2026/07/considerations-before-contacting-an-nih-program-officer-practical-guidance-using-health-disparities-science-as-a-representative-example

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