National Institutes of Health (NIH)

http://grants.nih.gov/grants/oer.htm

K08 Mentored Clinical Scientist Research Career Development


Grant-Writing Guidebook

Next NIH Regional Grant Writing Seminar May 15-17, 2019


We welcome your feedback. Please contact

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Information in this document is for guidance only and does not guarantee funding.
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Helpful Links

National Institute of Allergy and Infectious Diseases “Apply for a Grant”

https://www.niaid.nih.gov/grants-contracts/apply-grant

Enhancing Reproducibility through Rigor and Transparency


How to translate the application instructions to successfully demonstrate rigor in your application

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

Information for Reviewers:

https://grants.nih.gov/grants/policy/review.htm

Scoring Guidance (also see next page)


Reviewer Scoring

https://era.nih.gov/reviewer/critique_scores.cfm

Consolidated List of Reviewer Documents


Write Your Application

http://grants.nih.gov/grants/writing_application.htm

What Peer Reviewers Look For

http://ow.ly/SOSr30nRgbl

Peer Review Policies and Practices


NIH Glossary & Acronym List

http://grants.nih.gov/Grants/glossary.htm

Standard Due Dates for Competing Applications

http://grants.nih.gov/grants/funding/submissionschedule.htm

Page Limits

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#other

Biosketch

http://beckerguides.wustl.edu/NIH_Biosketch
Writing the Application

Tip #1

Learn from NIH-funded senior research investigators who have served on NIH study sections (review panels).

Beginning next page:

*Specific Aims* template from Laura J. Bierut, MD, Department of Psychiatry
Washington University School of Medicine
Think of your Specific Aims page as a summary of your entire grant with the general information and global significance, innovation, and approach.

The Introductory Paragraph

In this paragraph, your goal should be to introduce your research subject to the reviewers and quickly capture their attention. This paragraph should describe the significant gap in knowledge that directly relates to the critical need the funding entity deals with. It is critical to know your funding entity’s mission statement and ensure the critical need you are trying to fill fits well within its mission. It should include the following information:

First Sentence/Hook: In this sentence, briefly describe what your proposal will be about. Ideally, this sentence should convey a sense of importance or urgency to your research. Explain quickly WHAT your research topic is and WHY it is critical that you conduct the research (i.e. saving lives, preventing cancer, etc.)

“The overarching goal of is …..”

What is Known: State what is currently known in the specific field. This part should not be very long (3-5 sentences) but it should ground the reader in the subject of your research. Provide the reader with only the necessary details to understand why you are proposing the work. Remember to be concise and focused on only the key points.

Gap in Knowledge: The gap in knowledge is the piece of information that is not known. Clearly state the gap in knowledge that needs to be addressed. Convey that your research will fill this gap using the funding that you are requesting. This technique can be useful to emphasize the most important words or phrases in your Specific Aims page. If you choose to use italics or underline to emphasize key points, remember to do so moderately. Overuse of italics or underlining can be distracting.

“Currently, a major gap in the field is…..”

The Critical Need: The critical need is the knowledge (hypothesis-driven), technique, new compound, or treatment that you propose to develop. This need is important to increase medically relevant knowledge or improve health care. The critical need is the reason your proposal should be funded. Emphasize the significance of the problem you are trying to address. Additionally, it should be clear in this paragraph that your research proposes the next logical step to advance the field.

Circle back to the overall goal at the end of the paragraph.

The Second Paragraph

In this paragraph, your goal should be to introduce the solution that fills the gap in knowledge. It is critical to convince your reviewers that you (and your colleagues) have the solution to address the current knowledge gap and the expertise to accomplish this solution. Keep your wording simple, relevant, and to the point. You will want to address the following points:
• What do you want to do?
• Why are you doing it?
• How do you want to do it?

There is some flexibility in this paragraph, depending upon how your proposal is structured and what your goals are. For example, your research may be strictly hypothesis-driven and seek to test several elements of one general hypothesis. In other cases, you may be seeking to develop a critical tool or technique in the proposal. Based on these variations, this paragraph will shape up differently. However, it should include the following components:

**Long-Term Goal:** This is your overarching research goal. Because you are asking for support from a particular funding entity, it is important to ensure that your long-term goals align with the mission of your funding entity. Keep your wording general in this sentence—you are stating your long-term plans, and the reviewers understand that the specifics may be subject to change.

**Proposal Objectives:** State your central objectives clearly, specifically, and with simple language. Describe how your project addresses the critical need, and clearly state the proposed solution. In general, avoid vague objectives because it will be unclear to the reviewers what you expect to determine with the proposed research.

**Rationale:** Explain how you arrived at your central objectives (for example, using past studies and published literature). Briefly, state what your project’s completion would make possible (e.g., new therapeutics), and tie it to the funding entity’s mission.

**Qualifications:** Briefly state why your experimental design and your team are the best to accomplish the research goals. You can mention factors such as your preliminary data, personnel qualifications, laboratory equipment, etc., but it is important to keep it concise.

**The Aims**

In this section, you will describe briefly each of the aims you will use to meet your objectives. Ideally, the aims should be related, but not dependent, upon each other. If you do this, the failure of one aim (or an unexpected result from one aim) does not negatively influence any other aim or prevent the completion of the other aims.

Within 2-4 sentences each, you should describe the experimental approach and how each aim will help answer your larger objective. A typical NIH R01 grant will have between 2 and 4 Aims. Plan to describe each aim in a separate paragraph. Additionally, these tips may help you to formulate your aims sections:

• Give your aim an active title that clearly states the objective in relationship to the objective.
• To make it easier for the reviewers to clearly read and understand each aim, it is often helpful to use headings and/or bullets to delineate each specific aim.

**The Final Summary Paragraph**

This final paragraph of the Specific Aims is often overlooked, but it is vital for the impact of your proposal. This final paragraph creates a firm, broad base to support your entire proposal.
The final paragraph should include the following important details:

*Innovation:* Plainly state what is innovative about your project. What would completion of this proposal bring to the field that is not present currently?

*Expected Outcomes:* Specifically state your expected outcomes for this project. Use plain language. What do you expect to see at the completion of each aim? Include this information only if you have not placed it in the Aims.

*Impact:* State how your project would help those who need it, (i.e. the development of a new treatment, vaccine, disease model or diagnostic tool) Include a broad impact statement about how your proposal will benefit the people or other subjects that you mentioned in the opening paragraph.

Adapted from -


Laura Bierut
Writing the Application

Tip #2

Learn from NIH Center for Scientific Review staff

On next page:
Tips from presentations by the following NIH staff:

Rebekah S. Rasooly, PhD,
Fungai Chanetsa, PhD, MPH
Ronald Margolis, PhD
Amanda Boyce, PhD
Allan Willard, PhD
Anthony Coelho Jr., PhD
Henry Khachaturian, PhD

To learn more about the grant application and review process at the NIH:

2019 NIH Regional Seminars:
May 15-17, 2019, Baltimore, Maryland
November 6-8, 2019, Phoenix, Arizona

Hallmarks of an Outstanding K Grant Application

- Strong significance for an important problem in public health: IMPACT is high
- High degree of novelty and innovation
- Strong track record of a well-qualified applicant with compelling publications
- Clear rationale
- Relevant and supportive preliminary data
- Clear and focused approach that provides unambiguous results
- Careful attention to details: spelling, punctuation, grammar, fonts, clarity of data, error bars, spelling, etc.
- Always provide a career development timeline; state what skills you will gain with the K

Common Reasons Cited for a Weak Application

- Lack of or weak impact
- Significance not obvious or weak
- Too ambitious, lacking focus, too many unrelated aims
- Unclear or flawed hypothesis or rationale
- Applicant track record weak or lacking appropriate expertise
- Feasibility unsupported
- Approach flawed
- Poor writing and lots of errors

What Reviewers Look for in a K Grant Application

- Significance and impact, exciting ideas, clarity
- A compelling argument for why your career will be enhanced by a K award
- Ideas they can understand – don’t assume too much
- Realistic aims and timelines – don’t be overly ambitious
- Brevity with things that everybody knows
- Noted limitations of the study
- A clean, well-written application
- Make it easy for reviewers. Don’t make them work hard.
- Use major & minor section headings that altogether provide a summary of your work

Common Problems in 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 or overly ambitious amount of work
- Uncertainty concerning future directions
- Don’t propose too much – avoid an over-ambitious project or one that looks like an R01

What Determines Which Grants Get Funded?

- Scientific merit
- Program considerations
- Availability of funds
Writing the Application

Tip #3

Know what the reviewers will use to score your application.

Beginning next page:
Scoring guidelines
Example of a K08 reviewer critique template
Additional Scoring Guidance for Research Applications

The NIH scoring system was designed to encourage reliable scoring of applications. Reviewers or study sections who assign high ratings to all applications diminish their ability to communicate the scientific impact of an individual application. Therefore, reviewers who carefully consider the rating guidance below can improve the reliability of their scores as well as their ability to communicate the scientific impact of the applications reviewed.

The chart below was developed to encourage reviewers to consider strengths as well as weaknesses when evaluating applications for research grants and cooperative agreements.

### Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3 4 5 6 7 8 9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer’s judgment) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

- e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no weaknesses.
- e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
- e.g. Applications may be addressing a problem of moderate importance in the field, with some or no weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.
OVERALL IMPACT

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

<table>
<thead>
<tr>
<th>Overall Impact Score (1-9; see page 4 for score chart):</th>
<th>Score:</th>
</tr>
</thead>
</table>

Overall Impact Write a paragraph summarizing the factors that informed your Overall Impact score.

SCORED REVIEW CRITERIA

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

1. Candidate
   Strengths
   •
   Weaknesses
   •

2. Career Development Plan / Career Goals and Objectives
   Strengths
   •
   Weaknesses
3. Research Plan

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Weaknesses</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Weaknesses</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Environment & Institutional Commitment to the Candidate

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Weaknesses</td>
<td></td>
</tr>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Priority Scoring

Please document your recommended score. The score should reflect the overall impact that the project could have on the field based on consideration of the criteria.

9-Point Score Chart

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.
Provide an overall impact paragraph to articulate your assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved. Your paragraph should:

- Introduce the general objective of the project in one or two sentences
- State the level of impact the application will have and why (what is the major contribution/advance to be gained?).
- Identify the major score-driving factors that informed your assessment
- Explain how you balanced/combined/weighted the various criteria to arrive at the overall impact score

**Candidate**

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate’s prior training and research experience appropriate for this award?
- Is the candidate’s academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate’s commitment to meeting the program objectives to become an independent investigator in research?
- Do the letters of reference address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

**Career Development Plan/Career Goals and Objectives**

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate’s prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate’s research and career development progress?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

**Research Plan**

- 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 (formerly, scientific premise)?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to ensure the rigor of the proposed research and addressed 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?
- If proposed, will the clinical trial experience contribute to the proposed research project?

**Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)**

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, and/or collaborator’s previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
• Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

• If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

Environment & Institutional Commitment to the Candidate

• Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?

• Is the institutional commitment to the career development of the candidate appropriately strong?

• Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?

• Is the environment for scientific and professional development of the candidate of high quality?

• Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?
Writing the Application

Tip #4

Think of the 3 “Cs” when writing your application:

Correct: Complete all required sections using correct formatting

Concise: Use a direct, “active voice” writing style

Clean: Remove tracking and comment boxes before submitting

Beginning next page:

Writing and formatting guidance from the NIH
From the NIH


Font (size, color, type density) and Line Spacing

Adherence to font size, type density, line spacing and text color requirements is necessary to ensure readability and fairness. Although font requirements apply to all attachments, they are most important and most heavily scrutinized in attachments with page limits.

Text in your attachments must follow these minimum requirements:

- **Font size:** Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.
  - Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- **Type density:** Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line spacing:** Must be no more than six lines per vertical inch.
- **Text color:** No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

We recommended the following fonts, although other fonts (both serif and non-serif) are acceptable if they meet the above requirements.

- Arial
- Georgia
- Helvetica
- Palatino Linotype

Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

Format Pages

- Watch for form field instructions that refer you to specific format pages (e.g., biosketch, training data tables).

Grantsmanship

- Use English.
- Avoid jargon.
- Spell out acronyms the first time they are used in each application section/attachment and note the appropriate abbreviation in parentheses. The abbreviation may be used in the section/attachment thereafter.

Headers and Footers
Do not include headers or footers in your attachments. We will add headers, footers, page numbers, bookmarks and a table of contents when we assemble your grant application upon submission.

Headings (e.g., Significance, Innovation) within the text of your attachments improve readability and are highly encouraged.

Some funding opportunity announcement and form instructions provide guidance on organizing the content of attachments including specific headings that must be present.

Hyperlinks and URLs

Hyperlinks and URLs are only allowed when specifically noted in funding opportunity announcement (FOA) and form field instructions. The use of hyperlinks is typically limited to citing relevant publications in biosketches and publication lists. It is highly unusual for a FOA to allow links in Specific Aims, Research Strategy and other page-limited attachments.

Hyperlinks and URLs may not be used to provide information necessary to application review.

Reviewers are not obligated to view linked sites and are cautioned that they should not directly access a website (unless the link to the site was specifically requested in application instructions) as it could compromise their anonymity.

When allowed, you must hyperlink the actual URL text so it appears on the page rather than hiding the URL behind a specific word or phrase.

Examples:

- NIH (http://www.nih.gov/)
- http://www.nih.gov/

Images

Digital images of material such as electron micrographs or gels must only be included within the page limits of the Research Strategy. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5” x 11” page at normal (100%) scale.

Investigators must use image compression such as JPEG or PNG.

Marking up Attachments

Do not mark-up your PDF documents with comments, sticky notes or other features that are added on top of your PDF document content. This information may not be retained in your final application image.

Orientation

Both portrait and landscape attachments are accepted. However, keep in mind that landscape can be difficult to read online and may require reviewers and staff to scroll to see all available text.

Page Limits
Adhere to the page limits defined in the Table of Page Limits or within the text of the funding opportunity announcement (FOA).

Page limits defined in a FOA should be followed when different than those found in the Table of Page Limits.

If no page limit for an attachment is listed in either the Table of Page Limits or the Section IV of the FOA under page Limitations, you can assume the attachment does not have a limit.

We systematically check many page limit requirements and provide error or warning messages to minimize incomplete or non-compliant applications. These systematic checks may not address all page limit requirements for a specific FOA and do not replace the checks done by staff after submission. You must comply with all documented page limits.

Some page limits apply to multiple attachments that when combined must stay within a designated limit. You may want to prepare your information in a single document to ensure you are within the page limit and later break-up the information into the various separate attachments. Our systems will accommodate a certain amount of white space resulting from splitting the information into the separate attachments when verifying compliance with a limit.

Do not use the appendix or other sections of your application to circumvent page limits (NOT-OD-11-080).

Paper Size and Margins

- Use paper size no larger than standard letter paper size (8 ½" x 11").
- Provide at least one-half inch margins (½” ) - top, bottom, left, and right - for all pages. No applicant-supplied information can appear in the margins.

Scanning

- Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word-processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your application for agency analysis and reporting.
- We recognize that sometimes scanning is necessary, especially when including letters of support or other signed documents on business letterhead.

Security Features

- Our systems must be able to open and edit your attached documents in order to generate your assembled application image for agency processing and funding consideration.
- Disable all security features in your PDF documents. Do not encrypt or password protect your documents. Using these features to protect your documents also prevents us from opening and processing them.

Single vs. Multi-column Page Format

- A single-column page format easily adapts to various screen sizes and is highly encouraged.
- Multi-column formats, especially for information spanning multiple pages, can be problematic for online review.
Video

- Videos cannot be imbedded in an application, but are accepted under limited circumstances as post-submission material. See NOT-OD-12-141.
- When allowed, the application must be structured at the time of submission to indicate that a video will be submitted post-submission.
  - The cover letter submitted with the application must include information about the intent to submit a video; if this is not done, a video will not be accepted.
  - Key images, “stills” and a brief description of each video must be included within the page limits of the research strategy. Sufficient descriptive information must be provided within the research strategy to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.
Writing the Application

Tip #5

Review funded grants.

Sample Applications

National Institute of Allergy & Infectious Diseases
https://www.niaid.nih.gov/grants-contracts/sample-applications

Washington University School of Medicine grants library
https://crtc.wustl.edu/otg/grants-library/
Writing the Application

Tip #6

Build your own toolkit.

Beginning next page:

Candidate Information and Goals for Career Development template
Specific Aims template
Research Strategy template

Other Resources:

“Write Your Research Plan”

https://www.niaid.nih.gov/grants-contracts/write-research-plan#A7
K08 Application Template

https://researchtraining.nih.gov/programs/career-development/K08

Page limits:
Candidate Information and Goals for Career Development and Research Strategy (12 pages)
Specific Aims (1 page)

How to Use the Template: On the following pages, fill in the blank areas beneath each question, criterion and suggestion and delete the template text, leaving the bold-faced headings and narrative text. This template is to serve as a guideline only and should be modified as needed based on the specific research project, current published NIH guidelines, and NIH funding notice. When writing, consider the general review criteria below (repeated from page 14):

Candidate
- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the letters of reference address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan/Career Goals and Objectives
- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
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- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

Research Plan
- 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 (formerly, scientific premise)?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to ensure the rigor of the proposed research and addressed 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?
- If proposed, will the clinical trial experience contribute to the proposed research project?

Template (Arial 11point font) begins on next page and is adapted from the following K08 example:

“Antibody Mediated Mechanisms of Immune Modulation in Tuberculosis”
https://www.niaid.nih.gov/grants-contracts/sample-applications#K08

For additional funded examples, contact Karen Dodson at Karen.Dodson@wustl.edu
Candidate

My career goal is to....

My exposure to lab science began....

This interest extended into...

At this point in my career.....the K08 funding is a critical element to support my transition to independence from scientific and leadership aspects...

Important note: The following Specific Aims template was developed by funded investigators at Washington University School of Medicine. The template is a helpful guideline only and does not guarantee funding. You do not need to answer all of the questions and should only answer the questions that are relevant to your research study.

Specific Aims (limit 1 page)

• What is your project about? State your goal/objective/outcome.

• Why is it important? State the significance and overall impact.
  o Medical significance
  o Long-terms goal/objective of the project

• What is known? Provide background related to your research question.
  o This could include data from your lab as part of this background

• What is unknown? What do you hope to accomplish?

• Why is the gap in this knowledge a problem and how do you propose to address it?
  o Rationale of this study – why are you doing THIS project
  o What have you accomplished to date that suggests this approach? (Preliminary Data)

• What is your hypothesis (hypotheses)?
  o Objective of this application

• Explain how you will address your hypothesis (hypotheses) using your Specific Aims. (Suggested transition sentence to this section: "We proposed to address this (these) hypothesis (hypotheses) using the following specific aims:"). You may also list a hypothesis for each aim here.
  o Address “why” questions rather than “what”: no “demonstrate” or “describe” words should lead the aims, which should be very succinct and include expected outcomes
  o If you can briefly include an indication of the expected outcome/significance here, do so
  o KEEP THE AIMS SHORT – a full paragraph/aim is too much

• Overall Impact paragraph (the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved): what you propose to do,
  o Why it is relevant/SIGNIFICANT to medical science and the field
  o Why your research team is the best team for the project
Research Strategy

Significance (consider the following review criteria when writing the narrative for this section):
- Does the project address an important problem or a critical barrier to progress in the field?
- Is the prior research that serves as the key support for the proposed project rigorous (formerly, scientific premise)?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Innovation (consider the following review criteria when writing the narrative for this section):
- 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 of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach (consider the following review criteria when writing the narrative for this section):
- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- 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?
- Have the investigators presented adequate plans to ensure the rigor of the proposed research and addressed relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Aim 1: (repeat precise wording from the Specific Aims page here; include hypothesis if there is an individual hypothesis for each aim)
Rationale: _______________________
Hypothesis: _______________________
Preliminary Data: ___________________
Experimental Design: ___________________
Expected Results: ___________________
Potential pitfalls and alternative strategies: ___________________
Aim 2: (repeat precise wording from the Specific Aims page here; include hypothesis if there is an individual hypothesis for each aim)

Rationale: _______________________
Hypothesis: __________________________
Preliminary Data: ______________________
Experimental Design: ___________________
Expected Results: ______________________
Potential pitfalls and alternative strategies: ________________________________

Aim 3: (repeat precise wording from the Specific Aims page here; include hypothesis if there is an individual hypothesis for each aim)

Rationale: _______________________
Hypothesis: __________________________
Preliminary Data: ______________________
Experimental Design: ___________________
Expected Results: ______________________
Potential pitfalls and alternative strategies: ________________________________

Future Studies

Statistical Analysis

Timeline and feasibility

Biohazards

Training in the Responsible Conduct of Research*

***End Template***

*Training in the Responsible Conduct of Research  All K08 applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant’s career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) Format – the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) Subject Matter – the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) Faculty Participation – the role of the mentor(s) and other faculty involvement in the fellow’s instruction; 4) Duration of Instruction – the number of contact hours of instruction (at least eight contact hours are required); and 5) Frequency of Instruction – instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus rating of the review committee. See NOT-OD-10-019.