

NIH Grant Proposal Preparation:

R01 and F Applications

Where To Begin: General Instructions

Preparing an NIH grant application is a complex and lengthy process. Some of these steps will involve your interaction with a grants administration office at your institution. A person from this office can assist you in acquiring a **Commons ID** (which you will require for submission) as well as finding the program announcement for your NRSA application and the specific instructions that you will require to prepare all of the parts. The application is made electronically by submitting documents in **Adobe format** (you will require the proper Adobe version to complete these, presently versions 9-11) according to specific instructions located in the **424 instruction package**.

There are two different sorts of information that you will be required to provide in your application. Information of the first sort is **administrative** and it is to be typed into electronic forms that are a part of the submission package. You will fill out forms in this package in collaboration with institutional grant administrators. A representative of that office is present this morning and is prepared to speak to you. He/she will describe services that this office will provide.

Information of the second type relates to the **science of your proposal**. This information will be prepared as Word documents which you will print as PDFs and then load electronically into the submission package. We have prepared a PowerPoint presentation that will give you some specific instructions as to how each of these documents can be prepared.

I have provided below some general instructions that include [grants.gov](http://www.grants.gov) web sites that you should navigate to obtain application information. Start at [grants.gov](http://www.grants.gov). or just go to this link: <http://www.grants.gov/search/basic.do>. You'll have a list of possible searches.

Alternatively, go to:

<http://apply07.grants.gov/apply/opportunities/instructions/oppPA-11-111-cidADOBE-FORMS-B1-instructions.pdf>. Once you click on this URL, you are taken to a site with a PDF or Word version of the instructions. Download, read, and follow these carefully. This document has all of the information you will need, but you will need also to consult with an official from your university grants administration office for clarification or help.



U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ

A guide developed and maintained by NIH for preparing and submitting individual fellowship applications via Grants.gov to NIH and AHRQ using the SF424 (R&R)

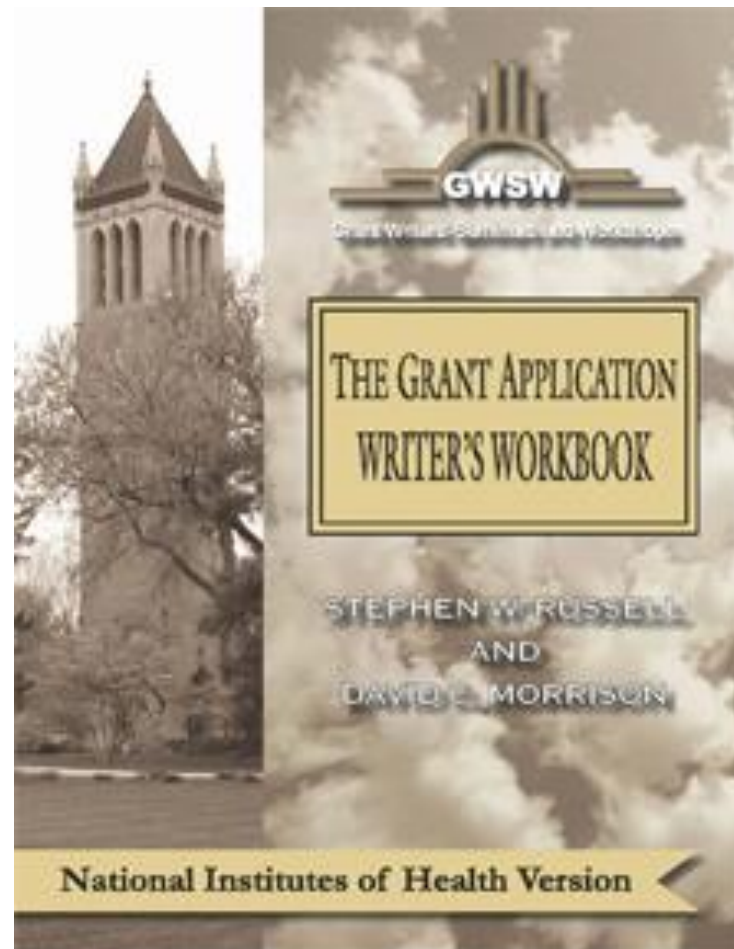
How to find the funding opportunity announcement

- Go to [grants.gov](https://www.grants.gov).
- On right side of screen you will see [Search: grant opportunity](#).
- Do basic search inserting the program announcement ([PA-16-309 for NRSA](#) or [PA-16-160 for RO1](#)). You will get the “[opportunity title](#)”. Click on that.
- The page that comes up has a field entitled “[application package](#)” (right side of screen).
- Click on “[application](#)” to get the forms you will need.
- Download [instructions and application](#).

Some Funding Opportunity Announcements

- F30- MD/PhD Predocs: **PA-16-306**
- F31- Predocs: There are a variety of options (diversity, Institute-specific) but the parent is **PA-16-309**
- F32- Postdocs: There are a few options but the parent is **PA16-307**
- F33 Senior Fellows: **PA-16-310**
- Parent R01: **PA-16-160**
- Parent R21: **PA-16-161**

There are a number of grant preparation workshops and workbooks found on the web. We have had particular success using a workbook entitled: *The Grant Application Writer's Workbook*. Copies can be obtained from grantcentral.com for about \$75-\$80. Much of what we present in our training materials is keyed to specific chapters in this workbook.



Preparation of individual sections of an RO1 proposal

- We will go through steps in the application preparation process in the order in which pages appear in the final proposal, even though you may choose not to prepare them in this order.
- Make reference to appropriate chapters the workbook and consult your grants administrator for details regarding the completion of form pages and scientific content documents.

Template for the Research Plan

Abstract (1/2 page. 30 lines)

Specific Aims (1 page)

Research Strategy (6 or 12 pages)

Significance (from ½ to 1 page)

Innovation (about ½ to 1 page, *but not required for NRSA applications*)

Approach (remainder of pages up to 6 or 12)

Aim I

Statement of hypothesis

Rationale that supports hypothesis

Literature

Preliminary data

Feasibility

Experimental design

Expected outcomes and Statistical analysis

Pitfalls and alternative plans

Aim II...

Timetable

Proposal Title

- Title should be **compelling and informative**.
- The title should be **relatively short, descriptive, and jargon-free**.
- It should be sufficiently flexible and general to encompass not only the experiments you propose but also other experiments that may accrue from the results that you will obtain.
- Title should **emphasize the payoff** of your research.
- See tips in **Chapter 18** of the workbook.

Project Summary/Abstract

- Must be less than 30 lines with margins of ½ inch on each side of the page.
- This is the most important part of the proposal, as it is the only part that everyone will read.
- Read carefully the instructions given in Chapter 19 of the workbook.
- This section must be succinct, pithy, and must convey all that is in the specific aims, but in less space. Work on this carefully.
- Use critical colleagues to re-review the content and form of this document multiple times. Choose individuals who are carefull and who are invested in your success.
- This document must pass the “grandma” test. It should be clear, compelling, and understandable. Your goal here is not to impress the study section with your “in depth” knowledge of the subject.

Narrative

- This is a PDF file of no more than **three or four sentences**.
- It is meant to be a lay description of what your proposal is about.
- It must pass the “grandma” test for clarity and impact.

Literature cited

- This is the literature that you cite in the body of your proposal.
- This section is best put together as a part of the writing process of your background/significance/rationale sections in the research plan.
- We suggest that you acquire a program such as *Endnote* which allows the citation list to be compiled at the same time that the text of the research plan is written. Academic versions of this program are available at reduced cost.
- The *Endnote* program has the capability of allowing the citation style to be modified easily. Choose the NIH grant format that is published with this package.
- If possible, it is always best to include citations in the text (rather than numbered citations) if space permits.

Facilities and other resources

- This section lists **laboratory facilities, animal science resources (ASC), computer, office, and clinical facilities**. These resources include the laboratory environment of your advisor/mentor/collaborator.
- Follow the examples and illustrations provided in **Chapter 15** of the workbook.

Equipment

- This is the **equipment that will be available to you** to perform the work that you propose.
- Follow suggestions for completion of this section in **Chapter 15** of the workbook.

CV and Personal Statement

- This is your personal information with you academic history. It should be as complete as possible, containing your **academic history, educational background, honors and special achievements, your undergraduate and graduate academic record, and your publications.**
- You must provide a personal statement that states why you are the best person to do the proposed work.
- Here is where **you must justify the importance of your training/experience** and what you hope to achieve when it is complete.
- CVs and personal statements must also be prepared by your advisor(s)/collaborators and submitted here as well.
- Note that these statements are on **standard forms** that are a part of the submission package. They are prepared as Word files and then uploaded as PDF files into the application package.

Biosketch Page

Forms and instructions are now available on the [SF 424 \(R&R\) Forms and Applications page](#). The new format extends the page limit from four to five pages, and allows researchers to describe up to five of their most significant contributions to science, along with the historical background that framed their research. Investigators can outline the central findings of prior work and the influence of those findings on the investigator's field. Investigators involved in Team Science are provided the opportunity to describe their specific role(s) in the work. Each description can be accompanied by a listing of up to four relevant peer-reviewed publications or other non-publication research products, including audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware that are relevant to the described contribution. In addition to the descriptions of specific contributions and documentation, researchers will be allowed to include a link to a full list of their published work as found in a publicly available digital database such as MyBibliography

Research Support

- This information is to be provided by a faculty advisor if you are applying for a K award. It is the **listing of grant support that will sustain your research project** during the period of your tenure as a trainee.
- This support must be sufficient to sustain your work

Specific Aims

- Refer to Estevez application and *Chapter 7, Grant Application Writer's Workbook*.
- Make a **bullet outline** to assist you in laying out its structure.

Suggestion below:

Introductory paragraph

Opening sentence

Current knowledge

Gap in knowledge/unmet need

Focus on goals

Long term goal

Objective of application

Central hypothesis and rationale

Specific Aims Paragraph

Aim I

Hypothesis

Methods

Experiments to be performed

Result

Aim II....

Payoff statement (How is the world benefitted by your work.)

Significance

- Refer to **Chapter 9** in the workbook.
- Positive effect that successful completion of your
- Should be no more that **½ - 1 page**.
- Can be divided into three parts:
 - Critical review of the literature** that describes an unmet need.
 - Statement of **significance**.
 - Discussion of benefits of your work**.

Innovation

- Significance **vs** Innovation: “Significance is the positive effect that something is likely to have on other things” “Innovation is a new and substantially different way of considering and addressing something which results in positive change.”*
*Grant Application Writers Workbook, P77.
- What is the norm (methodology, interpretation, mechanisms, etc.).
Document with citations.
- How does your approach depart from the **status quo**? Is it a paradigm shift?
- How will this departure **project to fundamental progress** in the field?
- Not required for NRSA, but if you have innovation, put it in the Significance section.

Approach

Aim I

Statement of hypothesis

Rationale that supports hypothesis

Literature

Impact

Preliminary data/feasibility

Experimental design

Expected outcomes and statistical analysis

Pitfalls and alternative plans

Aim II

Statement of hypothesis

Rationale that supports hypothesis

Literature

Impact

Preliminary data/feasibility

Experimental design

Expected outcomes and statistical analysis

Pitfalls and alternative plans

Timetable

Vertebrate Animals

- Read and follow the instructions in the 424 instruction package.
- **Proposed use of animals.** Here state the species, strains, ages, sex, and numbers of animals to be used by specific aim. If surgery is to be done, describe fully.
- **Justification for the use of vertebrate animals.** Justify why live animals must be used. Provide arguments why such techniques as modeling and cell culture may not be sufficient for your purposes.
- **Procedures to limit discomfort, pain, and distress.** What are the methods to be used. How do they avoid undue discomfort and pain.
- **Describe methods of euthanasia (required only if not consistent with AVMA guidelines).** How are animals to be treated either to take tissue or to kill them at the end of the experiment.

How is your proposal reviewed?

Scores are based on a 9-point rating scale

- Your proposal is submitted electronically to the Center for Scientific Review (CSR) which then assigns it to an appropriate study section.
- The study section Scientific Review Officer (SRO) will assign your grant to up to three reviewers. Before the meeting reviewers will submit preliminary written critiques together with an overall score to CSR for ranking.
- Score is based five general criteria: Significance, Investigator, Innovation, Approach, and Environment. 1 = exceptional; 9=poor. Only integers will be used for scoring
- Before the review meeting each assigned reviewer will give a preliminary impact/priority score to each of their assigned applications. These score will help the review committee determine which applications will be discussed at the review meeting. Only the proposals ranked in the upper 50% will be discussed at the meeting.
- At the time of the meeting, reviewers will be called upon to summarize the strengths and weaknesses of each proposal to which they were assigned. Based on this discussion each member of the study section (up to 25-30 reviewers) will vote an integer score in the range 1-9. Overall score for your grant is the average of these individual scores multiplied by 10.

RPG/R01/R03/R15/R21/R34 Review

If you cannot access the hyperlinks below,
visit <http://grants.nih.gov/grants/peer/critiques/rpg.htm>.

Application #:

Principal Investigator(s):

OVERALL IMPACT

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.

[Overall Impact](#) Write a paragraph summarizing the factors that informed your Overall Impact score.

SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

1. [Significance](#)

Strengths

-

Weaknesses

-

2. [Investigator\(s\)](#)

Strengths

-

Weaknesses

-

3. [Innovation](#)

Strengths

-

Weaknesses

-

4. [Approach](#)

Strengths

<ul style="list-style-type: none">• Weaknesses <ul style="list-style-type: none">•

5. Environment
Strengths <ul style="list-style-type: none">•
Weaknesses <ul style="list-style-type: none">•

ADDITIONAL REVIEW CRITERIA

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Responses for Protections for Human Subjects, Vertebrate Animals, and Biohazards are **required for all applications**.
- A response for Inclusion of Women, Minorities and Children is **required** for applications proposing Human Subjects Research.

Protections for Human Subjects
Click Here to Select
Comments (Required Unless Not Applicable): <ul style="list-style-type: none">•
Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
Click Here to Select
Comments (Required Unless Not Applicable): <ul style="list-style-type: none">○

Inclusion of Women, Minorities and Children Applicable Only for Human Subjects Research
Click Here to Select Gender Code
Click Here to Select Minority Code
Click Here to Select Children Code
Comments (Required Unless Not Applicable): <ul style="list-style-type: none">•

Vertebrate Animals
Click Here to Select
Comments (Required Unless Not Applicable):

<ul style="list-style-type: none">•

Biohazards
Click Here to Select
Comments (Required Unless Not Applicable):
<ul style="list-style-type: none">•

Resubmission
Comments (if applicable):
<ul style="list-style-type: none">•

Renewal
Comments (if applicable):
<ul style="list-style-type: none">•

Revision
Comments (if applicable):
<ul style="list-style-type: none">•

ADDITIONAL REVIEW CONSIDERATIONS

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Click Here to Select
Comments (Required Unless Not Applicable):
<ul style="list-style-type: none">•

Select Agents
Click Here to Select
Comments (Required if Unacceptable):
<ul style="list-style-type: none">•

Resource Sharing Plans
Click Here to Select

Comments (Required if Unacceptable):

-

[Budget and Period of Support](#)

Click Here to Select
Recommended budget modifications or possible overlap identified:

-

ADDITIONAL COMMENTS TO APPLICANT

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

[Additional Comments to Applicant](#) (Optional)

-

General Scoring Criteria

Impact	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Moderate	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Score	Descriptor	Significance Descriptors
1	Exceptional	Achieving the proposed aims is likely to advance the research field in profound and lasting ways
2	Outstanding	Achieving the proposed aims is likely to advance the research field in critically important ways
3	Excellent	Achieving the proposed aims is likely to advance the research field in important ways
4	Very Good	Achieving the proposed aims is likely to contribute substantially to the current knowledge base of the research field
5	Good	Achieving the proposed aims is likely to contribute meaningfully to the current knowledge base of the research field
6	Satisfactory	Achieving the proposed aims is likely to contribute somewhat to the current knowledge base of the research field
7	Fair	Achieving the proposed aims is likely to contribute only incrementally to the current knowledge base of the research field
8	Marginal	Achieving the proposed aims is likely to contribute only minimally to the current knowledge base of the research field
9	Poor	Achieving the proposed aims is unlikely to contribute in any way to the current knowledge base of the research field

Score	Descriptor	Investigator Descriptors
1	Exceptional	<p>The investigators are extremely well qualified to achieve the proposed aims.</p>
2	Outstanding	
3	Excellent	
4	Very Good	<p>The investigators are qualified to achieve the proposed aims.</p>
5	Good	
6	Satisfactory	
7	Fair	<p>The investigators do not appear to have adequate qualifications to achieve the proposed aims.</p>
8	Marginal	
9	Poor	

Score	Descriptor	Innovation Descriptors
1	Exceptional	Groundbreaking concepts, approaches, methodologies, or interventions that are novel for any research field
2	Outstanding	New concepts, approaches, methodologies, or interventions that are novel across broadly related research fields
3	Excellent	New concepts, approaches, methodologies, or interventions that are novel for this research field
4	Very Good	Extensive improvements of the current concepts, approaches, methodologies, or interventions that are novel for this research field
5	Good	Considerable improvements of the current concepts, approaches, methodologies, or interventions that are novel for this research field
6	Satisfactory	Modest improvements of the current concepts, approaches, methodologies, or interventions that are novel for this research field
7	Fair	Refinements of current the concepts, approaches, methodologies, or interventions of this research field
8	Marginal	Only minor refinements of the current concepts, approaches, methodologies, or interventions of this research field
9	Poor	No change of the current concepts, approaches, methodologies, or interventions of this research field

Score	Descriptor	Approach Descriptors
1	Exceptional	The approach has an extremely high likelihood of achieving the proposed aims
2	Outstanding	The approach has a very high likelihood of achieving the proposed aims
3	Excellent	The approach has a high likelihood of achieving the proposed aims
4	Very Good	The approach has a very good likelihood of achieving the proposed aims
5	Good	The approach has a good likelihood of achieving the proposed aims
6	Satisfactory	The approach appears likely to achieve the proposed aims
7	Fair	The approach appears likely to achieve many but not all of the proposed aims
8	Marginal	The approach is likely to achieve only some of the proposed aims
9	Poor	The approach is unlikely to achieve most of the proposed aims

Score	Descriptor	Environment Descriptors
1	Exceptional	The environment appears to provide outstanding resources to achieve the proposed aims, including uncommon or unique resources that facilitate achieving the proposed aims
2	Outstanding	
3	Excellent	
4	Very Good	The environment appears to provide the resources needed to achieve the proposed aims
5	Good	
6	Satisfactory	
7	Fair	The environment does not appear to provide resources needed to achieve the proposed aims
8	Marginal	
9	Poor	

9-Point Scoring (Overall Impact)

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	<p>Strengths</p> <p>Weaknesses</p>
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

Grant Training II
April 24 & 25, 2017

Sign up sheet

Name	Email address	Department	School	Clinical Science or Basic Science Research?	Interested in attending workshop in April?
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					
17.					
18.					
19.					

Training Sessions

- Trainees will be assigned to one of the two days.
- Breakfast will be available at 8:30 a.m. A sack lunch will be served at noon. Participants should plan to participate for complete training session, which is likely to last until the early afternoon.
- Trainees will bring fully prepared text of proposals stored either on a lap top or other storage device to the training session. Prepared text should include the following sections:
 - Abstract
 - Specific Aims
 - Significance
 - Innovation
 - Approach
- Full text versions of these sections will be projected on to a screen from an LCD projector for discussion. Facilitators and other trainees will comment on organization, style, and clarity of exposition.
- Trainees are encouraged to make modifications/corrections/additions/deletions in real time. Each grant will receive about an hour of discussion.