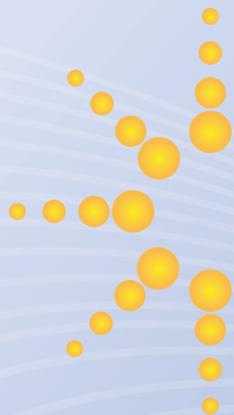


2013 Edition

# NIH R01

## Grant Application Mentor

*An Educational How-to Manual*



Principal  
Investigators  
Association™

## A Note from the Publisher

Dear Professional:

Thank you for ordering *NIH R01 Grant Application Mentor: An Educational How-to Manual* from the Principal Investigators Association Library. This resource is designed to help you better understand — and make the most of — your R01 grant application to the National Institutes of Health (NIH).

Dorothy Lewis, PhD, served as consulting editor and peer reviewed this report, and we gratefully acknowledge her input. Dr. Lewis has years of experience with the NIH application system and new methods of review. She has had continuous NIH funding since 1985, experiencing both times of multiple grants and times of reduced funding. She participated in multiple review panels related to HIV or flow cytometry in the 1990s. She served on the NIAID council from 2002-2006, on the DAIDS subcommittee, which exposed Dr. Lewis to policy matters and how topics are chosen by program. She currently is a member of the AIDS Immunology and Pathogenesis study section (2007-2011) and became chair in 2009.

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We are always on the lookout for interesting topics, researcher needs, and ways we can be of service to you. If you have a success story you would like to share with your colleagues, please do not hesitate to contact me. I would be delighted to hear from you, and I look forward to serving you and your organization with the best advice and information available in the future.

Best Regards,

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“NIH R01 Grant Application Mentor: An Educational How-to Manual” is published by Scientific Researchers Resources, Inc., 9990 Coconut Road, Suite 316, Bonita Springs, FL 34135 USA.

Telephone: (800) 303-0129 ~ Fax: (239) 676-0146 ~ Email: [info@principalinvestigators.org](mailto:info@principalinvestigators.org) ~ Website: [www.principalinvestigators.org](http://www.principalinvestigators.org)

This report is endorsed as a valuable tool for continuing professional development by Principal Investigators Association.

Founder: Leslie C. Norins, MD, PhD

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**Color Key:**

Throughout this report, we have used highlighted text to indicate the following:

 — original text by authors of this report  
(no color)

 — directly quoted NIH information  
(pink)

 — paraphrased NIH information  
(yellow)

 — directly quoted information from successful NIH grant applications  
(blue)

## Introduction

Applying for a National Institutes of Health (NIH) R01 grant is an involved process with many facets to consider and extensive guidelines to follow. This manual will guide you through the steps involved and help you submit the best proposal possible.

Of course, all research begins with an idea, and you must determine if yours should be funded by an R01 grant. Your research must meet NIH's priorities, but it is just as essential that the grant is the appropriate mechanism for your project.

Once you've verified that an R01 is right for you, you'll need to work out the specifics. Think about when to apply, what to title your proposal, and how to articulate your hypothesis. But before you actually begin, consider creating a writing schedule. Chapter 1 includes a sample timetable that will help you move through the steps of the application process more easily and manage your time effectively.

As you begin writing your proposal, remember the message you are trying to convey. You should explain your project thoroughly so readers will understand all aspects of it. But you also want to tell a compelling story and entice reviewers to approve your research.

Several chapters of this manual help guide you through the writing process. They offer advice for developing your Project Summary/Abstract, Biographical Sketch, Environment section and Research Plan. They also help you ensure your Research Strategy addresses your project's Innovation, Significance, Approach and Overall Impact.

When considering your project costs, refer to our chapter on creating a budget. You may also need to consult the section detailing considerations for special agents and human and animal subjects. Each chapter includes checks to ensure you're following NIH guidelines every step along the way.

Before you submit your application, take time to review it. Make certain you've included all the necessary components and adhered to all rules. You'll also need to correct any errors and remedy weaknesses before sending your proposal to NIH.

Once you've submitted your application, it goes through a comprehensive review. The final chapter of this manual delineates that process. It also explains what NIH scores mean and what steps you can take after you receive them

## Chapter 1: Starting the Grant Application Process

Before you can begin filling in your National Institutes of Health (NIH) grant application, there are several steps you must take first. For instance, you have to define the research project idea for which you are seeking funding. This may seem rather obvious, but the process for doing so is anything but simple.

You will also have to determine whether your research project will even qualify for an NIH grant, and several factors influence that determination.

Then — before you write a single word of your application — you should map out a strategy for it, which can include the following:

- Determining if the R01 grant mechanism is right for you.
- Picking a research project that you feel passionate about, yet which meets NIH funding priorities at the same time.
- Choosing people with expertise and experience who can advise you as you work on your application.

Next, you will need to more clearly define your proposed research project. NIH has specific criteria for investigators it will support, and there are explicit concepts every grant application must include to be considered. For instance, how you formulate your project title and hypothesis can significantly influence your research's fundability.

Finally, you should develop a writing schedule to ensure that your grant application meets NIH's submission deadlines. There are several possible tactics that you may use to help you.

Now, let's walk through each of the steps.

## QUALIFYING FOR AN NIH GRANT

You may have an amazing research idea that will shake the very roots of the scientific world, but if it does not meet the requirements set out by the NIH and its Institutes, Centers and Offices (ICOs), your application will not get past the initial review.

First, every application topic must be consistent with the NIH mission statement:

“NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.”

The goals of the agency are:

- to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
- to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

- in the causes, diagnosis, prevention, and cure of human diseases;
- in the processes of human growth and development;
- in the biological effects of environmental contaminants;
- in the understanding of mental, addictive and physical disorders; and
- in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

## What this means:

The agency states that its goals include the following:

- Foster fundamental creative discoveries, innovative research strategies and their applications as a basis for ultimately protecting and improving health;
- Develop, maintain, and review scientific human and physical resources that will ensure the nation's capability to prevent disease;
- Expand the knowledge base in medical and associated sciences to enhance the nation's economic well-being and ensure a continued high return on the public investment in research; and
- Exemplify and promote the highest level of scientific integrity, public accountability and social responsibility in the conduct of science.

As a result, NIH indicates that it will conduct and support research in the following areas:

- Causes, diagnosis, prevention and cure of human diseases;
- Processes of human growth and development;
- Biological effects of environmental contaminants;
- Understanding of mental, addictive and physical disorders; and
- Directing programs for the collection, dissemination and exchange of information in medicine and health, including development and support of medical libraries and the training of medical librarians and other health information specialists.

On the other hand, the agency would not fund projects like the following:

- Devising strategies to conserve water resources;
- Projects related to environmental pollution but unrelated to human health, such as floating plastic debris in the ocean or carbon dioxide absorption by concrete; and
- Research regarding dynamic water processes as they affect climate and environmental change.

Consequently, your initial step must be to review the above qualifying elements



### TIP:

Review NIH's qualifying elements and compare them to your proposed research idea to make sure they match up before you move forward with your grant application.

and compare them to your proposed research idea. If there is a good match, then you should move forward with your grant application.

If your proposed research does not meet NIH mission or other requirements, however, you should consider seeking a grant award from another source, such as the National Science Foundation (NSF). For example, NIH might fund computer-modeling research that seeks to predict the structure of cellular proteins and the spread or containment of infectious diseases, such as avian flu. Whereas NSF-sponsored research in math and computer modeling more likely would be used to design a concert hall, simulate weather patterns and assemble an investment portfolio that reduces risk and maximizes reward.

### **Institutes, Centers and Offices (ICOs) Also Weigh in**

Next, you must consider that NIH is made up of 27 semiautonomous ICOs. And each of these has its own defined research focus.

The NIH's Center for Scientific Review (CSR) staff performs the initial review of your grant application before assigning it to one of its review panels called Study Sections, which are organized around specific scientific subject matter. Nonetheless, you can suggest that a specific Study Section review your application, even though the CSR has the final decision.

Of the 27 ICOs, the following accept R01 grant applications for investigator-initiated research proposals:

**National Center for Advancing Translational Sciences** (NCATS, [www.ncats.nih.gov](http://www.ncats.nih.gov)) — The NCATS will focus on using science to create powerful new tools and technologies that can be adopted widely by translational researchers in all sectors.

**National Cancer Institute** (NCI, [www.cancer.gov](http://www.cancer.gov)) — Through basic and clinical biomedical research and training, the NCI conducts and supports research regarding cancer prevention and/or manageability, early-stage identification, innovative treatment development.

**National Eye Institute** (NEI, [www.nei.nih.gov](http://www.nei.nih.gov)) — NEI conducts and supports research that seeks to prevent and treat eye diseases and other vision disorders, including sight-saving treatments, visual impairment and blindness reduction, and quality-of-life improvements.

**END OF CHAPTER 1 PREVIEW**

## Chapter 2: Outlining Your Project and Individual Qualifications

There are specific sections of the National Institutes of Health's (NIH's) R01 grant application that allow you to outline your research topic and direction.

As you approach these areas, think of yourself as a storyteller. You are trying to get the reviewers emotionally involved to the point that they champion your proposal. All good stories have a resolution. Yours will be how your research will advance the scientific field and enable future investigations.

Your story begins with a Project Summary/Abstract, which is a brief yet detailed account of your proposed research. This section is important because initial NIH reviewers will use it to determine the study section that reviews your application. In addition, the Project Summary is the only section of your proposal that every reviewer reads. Most of them will scan the rest of your application, but they all read your Abstract in its entirety.

This chapter tells you what to include and what to leave out of your Project Summary. It also details NIH guidelines pertaining to Abstracts — such as the maximum number of pages — and gives you examples that illustrate what NIH wants to see.

We also examine the Biographical Sketch section, which is more than a simple biography of the principal investigator (PI). There are ways you can creatively use this area to increase your chances of successfully obtaining funding.

The Biographical Sketch section must include a personal statement, an account of the PI's positions and honors, a list of peer-reviewed publications or manuscripts in press, and research support. This chapter describes each of these elements and how to effectively include them in your Biographical Sketch.

In addition, we explore the requirements for proposals with multiple PIs. You must provide a rationale for using this approach and a description of your plans for making it work. This chapter includes examples of appropriate documentation for applications with multiple PIs.

The chapter also explains how letters of support can help new investigators applying for an R01 grant. It offers suggestions for the type of individual to provide a letter of support, clarifies why you should write the first draft of the letter for these individuals, and includes tips for crafting effective support letters.

## FORMULATING YOUR PROJECT SUMMARY/ABSTRACT

**Direct from NIH:** The NIH Application Guides states:

### Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. Please click the Add Attachment button to the right of this field to complete this entry.

The **Project Summary** is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at <http://report.nih.gov>) and will become public information.

The attachment must be in PDF format. (See Section 2.6 for additional information on preparing attachments.)

### What this means:

NIH states that your Project Summary/Abstract should be “a succinct and accurate description of the proposed work when separated from the application.” Further, “it should be a self-contained description of the project and should contain a statement of objectives and methods to be employed.” It should also outline your application’s broader, long-term goals and specific aims, as well as reference how your proposed research relates to human health, NIH says.

The agency also indicates that your intended audience for this section includes those “working in the same or related fields and insofar as possible [this section] should be understandable to a scientifically or technically literate lay reader.” You can expect all of the peer reviewers to read this portion of your grant application.

At the same time, NIH warns that you should not include any proprietary or confidential information or trade secrets in the Project Summary. If your proposal receives funding, the summary becomes part of the public record.

**Format Note:** The Project Summary can be no longer than 30 lines of text. You must use the Arial, Helvetica, Palatino Linotype or Georgia font in black at 11 point size or larger. You may use a symbol font to insert Greek letters or special characters, but the font size requirement still applies. In addition, there can be no more than 15 characters — including characters *and* spaces — per inch. And there can be no more than six lines of text per inch, using at least half-inch margins on all sides of the 8½” x 11” page.

Keep in mind that initial reviewers in the Center for Scientific Research (CSR) likely will use the Project Summary/Abstract to assign your application to a particular Scientific Review Group (SRG) or study section, as well as to the peer reviewers who will examine it. Therefore, it should contain certain keywords so that SRG staff can readily assign your application and NIH computer systems can retrieve your grant properly. And SRG members who are not primary reviewers probably will rely heavily on your summary to understand your proposal during the group’s general meeting to discuss application fundability.

END OF CHAPTER 2 PREVIEW

## Chapter 3: Showing Your Institution's Resources and Commitment

One of the core criteria National Institutes of Health (NIH) reviewers use to score your grant application is the Environment in which you perform the research.

They want to ensure you will have the resources — meaning the institutional support, equipment and physical items — you need to successfully complete your proposed investigation. Additionally, they want to know of any unique features of your scientific environment, subject populations or collaborative arrangements that will benefit your project. You will detail these elements in the Facilities and Other Resources and Equipment sections of the short-form application.

Where you perform your research has not always been so important. In fact, reviewers note that “environment is one of the review criteria that used to be virtually meaningless. Almost nobody got a bad score for it.” As one characterized it, “The only place that a reviewer could find information about [it] was the list of centrifuges and computers, which is really not very helpful.”

Obviously, this is no longer the case.

## DETAIL YOUR FACILITIES AND OTHER RESOURCES

**Direct from NIH:** The NIH Application Guide states:

### Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the Add Attachment button to the right of this field to complete this entry.

No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, Section 11 (Select Agent Research).

## What this means:

As you construct the Facilities and Other Resources section, you should answer the following questions:

1. What facilities will you use? Include the following subheadings and describe the capacities (including square footage), pertinent capabilities, relative proximity and extent of availability of each to your project:
  - Laboratory
  - Clinical
  - Animal
  - Computer
  - Office
  - Other, such as machine shop, electronic shop, etc.
2. How will the scientific environment in which you perform your research contribute to your success? Include the following sections, and describe how your studies benefit from unique features of the scientific environment or subject populations and useful collaborative arrangement:
  - Institutional support
  - Physical resources
  - Intellectual rapport
3. For early-stage investigators, describe the following:
  - Institutional investment in your success — for instance, resources for classes, travel and training
  - Collegial support, such as career-enrichment programs, and availability of organized peer groups
  - Logistical support — for example, administrative management and oversight and best-practices training, and financial support such as protected time for research with salary support
4. If there are multiple sites where your research will be performed, describe the resources available at each site.

5. Detail any special facilities you will use for working with biohazards or other potentially dangerous substances. If you are using anything classified as a Select Agent, be sure to describe any special facilities used for working with these substances.

For this section, you should list any distinctive features, which may include the following:

- A unique set of technical capabilities
- Access to a special patient population
- The collaborative nature of interactions between you and your colleagues
- A particular emphasis in a special area, such as neurobiology

This not only informs reviewers how your institution supports your research, but also underscores your qualifications as the best person to perform your proposed research. For early-stage investigators in particular, reviewers look for evidence of how your institution values your research and its level of commitment to helping you succeed.

In addition, first-time applicants often find succeeding with a proposal rather challenging. They frequently need assistance with start-up funds, access to graduate students, or departmental support for travel, training, or career-enrichment programs.

And if you are an early-stage investigator still working at the same institution where you performed your postdoctoral work, NIH reviewers may be skeptical of your application — especially if you are nearly in the same research area and your postdoctoral mentor still has active grants. A reviewer likely will wonder if the funds might indirectly benefit the mentor instead of funding you. You must demonstrate that you are independent and that your proposed research is *your* project.

Reviewers may also be skeptical when you are a long-term postdoctoral researcher and your institution offers to make you a research assistant professor — *if* you get a grant. NIH wants to see that your institution has already made you a research assistant professor, not that it is making its commitment to you contingent upon you getting the grant.



### TIP:

For early-stage investigators, reviewers look for evidence of how your institution values your research and its level of commitment to helping you succeed.

## Chapter 4: Proving Your Research Topic's Significance

Probably the most important parts of your National Institutes of Health (NIH) R01 application are those in which you describe your proposed research. Specifically, these are the Specific Aims and Research Strategy sections. They address your project's Significance, Innovation and Approach, which are three of the five core grant criteria that reviewers use to score your application.

At the same time, these sections will heavily influence your application's Overall Impact score. Unfortunately, there is no template for incorporating overall impact into your application, and there is no section called "Overall Impact" — or even an incentive to simply add a paragraph labeled as such. Instead, the NIH Office of Extramural Research has stated that you should describe "impact" clearly in the words you feel are relevant to your project.

Consequently, we will examine how you can use the Specific Aims and Research Strategy to perform double-duty:

1. Fulfill the Significance, Innovation and Approach criteria
2. Support the Overall Impact of your research

As you address each of these sections, note that NIH limits your Specific Aims to no longer than one page, and the Research Strategy cannot exceed 12 pages for an R01 application.

### Language Is Important

Also keep in mind that although terms like "aims," "goals," and "objectives" may seem interchangeable, they have separate meanings within your application.

- **Goals** are strategic and high-level. For instance, "Our goal is to understand signal transduction in breast cancer."
- **Objectives** often are a restatement of your hypothesis in a way that can be falsifiable. For example, if our hypothesis is that the EGF receptor axis is key in mediating steroidal effects on proliferation, your objective would be to determine the mechanism by which that occurs.

- **Aims** are the outlines of your tactics or tasks to be performed. For instance, “Aim 1 is to establish a culture system of primary breast epithelial cells,” or “I have accomplished this aim.”

Or think of it using this analogy:

- Goals are the view from 30,000 feet
- Objectives are the view from 10,000 feet
- Specific Aims are the view from 1,000 feet

## SPECIFIC AIMS NAIL DOWN THE STEPS

### Direct from NIH:

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Specific Aims are limited to one page.

### What this means:

In this section, NIH indicates that you should briefly list your research's specific objectives, which may include the following:

- Test your hypothesis
- Solve a specific challenge
- Challenge an existing paradigm or clinical practice
- Address a critical barrier to progress in the field
- Develop new technology.

Individual NIH Institutes, Centers or Offices (ICOs) may have additional suggestions for crafting your Specific Aims. For instance, the National Cancer Institute (NCI) indicates that your Specific Aims should cover the following:

- Broad, long-term goals;
- Specific objectives and hypotheses to be tested;
- Expected outcomes; and
- Impact on the research field.

NCI further recommends that your Specific Aims should include the following sections:

1. Brief narrative to describe the project's long-term goals and the hypothesis(es) to be tested, which you should adequately support with citations and preliminary data. Explain how you will use the results to test the hypothesis.
2. Numbered list of the aims. For clarity, each aim should consist of only one sentence. Use a brief paragraph under each aim if you need to provide detail. Most successful applications have two to four Specific Aims. And be sure that all aims are related — but not necessarily dependent upon each other.
3. Brief statement regarding the overall impact of the research.



### TIP:

Keep in mind that reviewers usually receive a small, focused project better than a diffuse, multifaceted project.

Keep in mind that reviewers usually receive a small, focused project better than a diffuse, multifaceted project.

Some reviewers have called the Specific Aims the most important page in your entire application because it may be the only section unassigned reviewers read to understand your Approach, Innovation and Overall Impact. They may make up their minds immediately whether your work should receive funding, and then read the rest of your proposal searching for details to reinforce their initial opinions.

If they immediately determine that they like your project, they will look for supportive points they can put in their review. On the other hand, if they decide they do not like it, they probably will begin to search for faults.

The Specific Aims is a one-page document that you will upload in the Research Plan Attachments area of the application.

**Format Note:** The Specific Aims section must follow the general application formatting requirements. You must use one of the following fonts in 11 point size or larger:

- Arial
- Helvetica
- Palatino Linotype or
- Georgia

You may use a symbol font to insert Greek letters or special characters, but the font size requirement still applies. In addition, there can be no more than 15 characters — including characters *and* spaces — per inch. And there can be no more than six lines of text per inch, using at least half-inch margins on all sides of the 8½” x 11” page.

## Overcome Specific Aims Challenges

There are several common challenges that applicants face — and proven ways to overcome them — that specifically apply to their Specific Aims, including the following:

**Challenge 1:** If your reviewer reads your Specific Aims and finds them interesting but remains unconvinced, she likely will read the rest of your application to determine if your project is feasible. Therefore, be sure to end the page with a brief paragraph that states your work’s impact — that is, how your project, if successful, will change your field of research. Spelling this out for the reviewer allows them to easily grasp your proposal’s strengths without having to work for it.

For example: “These two innovative methods, as well as the expertise of the team assembled, will combine to examine whether microparticles can offer important windows on the physiologic world of pregnancy and preeclampsia and set the stage for further longitudinal studies that seek to predict preeclampsia to allow for early treatment.”

**Challenge 2:** Reviewers often make the following comment on the summary statement: “If the first specific aim doesn’t work, the whole proposal goes out the window. If the researcher doesn’t get a positive result with it, he or she can’t do aims 2 or 3, so we’re not going to fund this until we see the data that have basically finished Aim 1.”

If the aims follow each other so that Aim 2 follows Aim 1 and Aim 3 follows Aim 2, you must tell the reviewers what you intend to do if you get an unexpected result with Aim 1. Convince them that there is a future to your proposal nonetheless.

The best grant applications are those with interconnected — but not interdependent — aims. Reviewers look for those experiments where the results do not particularly matter because the various outcomes are equally interesting.



### **STRATEGY:**

If the aims follow each other so that Aim 2 follows Aim 1 and Aim 3 follows Aim 2, you must tell the reviewers what you intend to do if you get an unexpected result with Aim 1.

## Chapter 5: Special Considerations

When outlining your project, if you plan to use human or animal test subjects — or sample or data from them — you must complete the key portions of the application associated with these groups.

Both you and your institution must assure NIH that human and animal test subjects will be protected. NIH cannot award any grant until such assurances are on file with the agency.

Include enough information so reviewers will have no questions about what you propose to do. In addition, your research plan must be certified by your institutional review board (IRB) prior to funding. Although you do not need IRB approval when you submit your application, you should begin the approval process early because revisions and final approval can take time.

And before NIH can fund your grant application, there must be a Human Subject Assurance on file with the Office of Human Research Protections. This is usually handled at the institutional level.

Similarly, for proposed research using vertebrate animals, there is specific information you must include regarding the animals' treatment and the rationale for including them. Also, an institutional animal care and use committee (IACUC) must review and approve your proposal before you submit it. At NIH, an Animal Welfare Assurance must be on file with the Office of Laboratory Animal Welfare (OLAW).

## COMPLETE THE INCLUSION ENROLLMENT REPORT

### Direct from NIH:

All new clinical research studies should collect and report information on participants with respect to two categories of ethnicity and five categories of race. The Inclusion Enrollment Report ([http://grants.nih.gov/grants/funding/424/SF424R-R\\_enrollmentreport.doc](http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc)) for reporting summary data on participants to NIH includes two categories of ethnicity and five categories of race and is based on the Office of Management and Budget (OMB) reporting standards for data on race and ethnicity. Investigators should review the instructions and Frequently Asked Questions about using the Enrollment Table format at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>.

When reporting these data in the aggregate, investigators should report: (a) the number of research participants in each ethnic category; (b) the number of research participants who selected only one category for each of the five racial categories; (c) the total number of research participants who selected multiple racial categories reported as the “number selecting more than one race,” and (d) the number of research participants in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed data should be compiled in a way that they can be reported using the required categories ...

### **If Data Collection is Ongoing, Such that New Human Subjects Will be Enrolled and/or Additional Data Will be Collected from Human Subjects:**

Investigators should report ethnicity/race and sex/gender sample composition using the Inclusion Enrollment Report.

### **If Data Collection is Complete, Such that No New/Additional Subject Contact is Planned:**

Investigators should use the Inclusion Enrollment Report ...

### *B. Renewal Application and Progress Reports*

The Inclusion Enrollment Report ([http://grants.nih.gov/grants/funding/424/SF424R-R\\_enrollmentreport.doc](http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc)) must be used for reporting accrual data to the NIH. For Revision applications, any proposed additions to the Targeted/Planned Enrollment Tables should be provided, in addition to the Inclusion Enrollment Report. In annual progress reports, investigators conducting clinical research are required to provide the cumulative total enrollment of subjects to-date, showing the distribution by ethnic/racial categories and sex/gender on the Inclusion Enrollment Report, and must update the Targeted/Planned Enrollment Table as needed.

### **What it means:**

If your application is a renewal or revision and involves clinical research studies, you must attach an Inclusion Enrollment Report. This allows you to include summary data on participants and involves two categories of ethnicity and five racial categories — all based upon Office of Management and Budget (OMB) reporting standards for race and ethnicity data.

NIH requires four pieces of information in this report:

1. The number of research participants in each ethnic category;
2. The number of research participants who selected only one category of each of the five racial categories;
3. The total number of research participants who selected multiple racial categories reported as the “number selecting more than one race”; and
4. The number of research participants in each racial category who are Hispanic or Latino.

And the agency would like for you to use the following form to submit the information:

## Chapter 6: Budgeting Your Research

When applying for a National Institutes of Health (NIH) grant, in addition to your proposal's science, you also have to forecast how much money you will need to complete your research. Therefore, you should use the budget and associated justifications to present and support all the expenses required to achieve your proposal's objectives.

In fact, your budget's numbers are almost as important as — if not more so — the words you use to tell your research's story. This part of your application communicates to reviewers what you plan to do with the money you are asking them to invest in your project. Some reviewers even flip to the budget first to get a snapshot of the proposal and help them understand it. Although they should not take your budget into consideration as part of the assessment process, the information is available to them. And reviewers are told to evaluate the application and assign a priority score based upon the science and feasibility, and some believe the budget an indicator of feasibility.

There are two types of budget proposals that you can submit:

1. Modular budget
2. Detailed budget

You can use a modular budget for certain research grants if you request \$250,000 or less per year for direct costs. These are simplified, so you would not submit detailed categorical information with these applications. You will input details about this type of budget beginning on page 18 of the R01 form PHS 398

Detailed budgets — also called research and related (R&R) budgets — involve filling out three separate data entry screens as part of the R01 grant application. And there are a total of 11 different sections that make up the three data screens. In addition, you have to complete a separate detailed budget for each year of support you request. So this can become a rather lengthy process.

Finally, your application's budget, regardless of the type you use, also includes several justification documents. These are narratives that you construct to indicate where you propose to spend your grant-related funds and why.



### **REMEMBER:**

Some reviewers flip to the budget first to get a snapshot of the proposal that will help them understand it.

## Direct vs. Indirect Costs

For budgeting purposes, NIH makes a distinction between “direct” and “indirect” costs associated with your proposal:

- Direct costs — Those that can be specifically identified with a particular project or activity.
- Indirect costs — Also called facilities and administrative (F&A) costs, the grantee incurs these for common or joint objectives that cannot be identified specifically with a particular project or program.

When formulating a modular budget, you should consider only direct costs. For detailed budgets, however, you must include both direct and indirect costs. Keep in mind, however, that universities and other institutions commonly establish a single, negotiated contracted percentage rate to represent F&A costs for all NIH grants on their campuses, and you can obtain that information directly from your organization to include with your application’s budget.

Note: From whatever award money you are granted, your administration will “take off the top,” for itself, the F&A percentage it has negotiated with the government.

Also remember that if you have a subcontract or consortium agreement with another institution, you should treat any costs associated with that agreement as “direct,” including that subcontracted organization’s indirect costs.

## STRATEGY FOR PLANNING YOUR BUDGET

The NIH short-form application includes both R&R and modular budget components, and you can use these to continually revise and keep track of your budget's size during your application writing process. In fact, this can be a helpful tool in your budget planning process.

And the National Institute of Allergy and Infectious Diseases (NIAID) suggests that you should expect to spend time and effort crafting your thorough justification for your budget. “The more detail you include to justify it, the better — weak budget justifications are a big problem for many applications,” the institute states.

If your budget expands beyond your grant type or career stage, you should consider cutting back your experiments or Specific Aims, experts recommend.

Also, remember that NIH allows you to use grant money for certain specific costs, and it uses the following principles to define which costs you can charge to your grants:

- **Allowable** — Also known as “conformance,” this principle centers on complying with the limitations and exclusions contained in the terms and conditions of the award, which can vary depending upon the type of activity, recipient and other characteristics of the specific grant.
- **Allocable** — You can allocate a cost to your grant if you incur it solely to advance work under the proposal, it benefits both the project and other work at your institution, or it is necessary to the overall organizational operation and is assignable to the grant at least partially.
- **Reasonable** — A cost may be reasonable if it and its associated costs reflect an action a prudent person would take under the circumstances prevailing when the decision to incur the cost was made.
- **Consistency** — You, as the Principal Investigator (PI), must consistently assign costs to cost objectives.

These four principles apply regardless of the type of budget you use.



## STRATEGY:

You should ask only for enough money to do the work you propose, but do not think that a “low ball,” unrealistic budget will curry favor.

## UPDATE:

On January 20, 2012, NIH released a notice for **Salary Limitation on Grants, Cooperative Agreements, and Contracts** (NOT-OD-12-035). For additional information, please go to: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>

Another key aspect to your budget strategy is knowing how much money to request. As the “Goldilocks” fairytale says, “Not too much, not too little, but just right.” You should ask only for enough money to do the work you propose, but do not think that a “low ball,” unrealistic budget will curry favor. In fact, you should keep the following in mind:

- NIH reviewers search grant applications for reasonable costs and judge proposals based on whether your Specific Aims and methods support your request.
- Reviewers also read the percent effort you list for each key person and judge whether they are in sync with their expectations based upon your application.
- If you significantly over- or underestimate your budget, reviewers often take this as you not understanding your work’s scope.

Consequently, NIAID recommends that you should calculate salaries as 60 percent to 80 percent of your total budget request. When you formulate the PI’s salary, remember the mandatory cap, which changes each year. You can find the salary cap information on NIH’s Web site: [http://grants.nih.gov/grants/policy/salcap\\_summary.htm](http://grants.nih.gov/grants/policy/salcap_summary.htm). And do not ask for anything that might appear extravagant, such as too much travel.

You should also use your budget to mention any discounts you receive. For example, you use a large number of antibodies from a single source for your project, and that supplier gives you a 25 percent volume discount. You should note this in your budget documents because reviewers will want to know that you have established this relationship.

NIAID also recommends that you should not request funds for equipment or resources you have already listed as available in your Research and Other Related Project Information forms. If you do, reviewers will delete these items, and it may tarnish your credibility.

Alternatively, once you have determined the resources you will need for your project, identify what your institution can provide. Once you have this information, NIAID recommends that you ask the following:

## Chapter 7: Submitting Your Application

Before you submit your R01 application, take time to review the finished product. Make sure your proposal works as a whole rather than a group of parts. Remember your ultimate goal is to communicate that your research deserves funding, you're the right person to conduct it, and your institution is the right place to do it.

That's why reviewing your proposal for content is important. Ensure all of the sections communicate your message adequately. Your research strategy must include strong specific aims and address your project's significance, innovation and approach. Your project summary should be a compelling synopsis of your proposed research. And your budget should be in synch with your research strategy.

Reviewing your proposal for writing quality is just as important. You may want to ask colleagues or non-experts to read your proposal and provide feedback. Or you may need to hire a professional editor.

You must also construct a cover letter to introduce your proposal. This is part of the National Institutes of Health's (NIH's) application upload process, and the agency encourages you to include one. If you are submitting a changed or corrected application, the cover letter is mandatory.

In addition, make sure you have included all of your application's necessary components. Don't forget any attachments, and confirm that all attachments adhere to NIH requirements. The agency used to provide a two-day window during which applicants could fix errors, but that is no longer available. Therefore, it is extremely important to ensure all of your documents are uploaded.



### **TIP:**

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Your Research Strategy must include strong Specific Aims and address your project's Significance, Innovation and Approach.

## Include All the Necessary Components

Arguably the most important step in reviewing your R01 application is making sure it is complete. There are certain components that are mandatory for all applicants, and there are parts that are required only under certain circumstances.

### Direct from NIH:

A completed application includes data in the following components:

### Required Components

- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist
- PHS398 Modular Budget or Research & Related Budget, as appropriate

### Optional Components

- PHS398 Cover Letter File
- Research & Related Subaward Budget Attachment(s) Form

For certain applicants, NIH requires additional components. You must take extra steps if your research involves multiple institutions or requires multiple principal investigators (PIs). The same is true if you are submitting a revision application or if you belong to a foreign institution applying for U.S. dollars.

## Foreign Organizations

Applicants from foreign organizations must:

- Prepare their budgets in U.S. dollars
- Create detailed budgets for all applications (complete the research and related budget component of the SF424 application forms, not the PHS398 modular budget component)
- Omit any charge-back of customs and import fees
- Comply with the format specifications, which are based upon a standard U.S. paper size of 8.5” x 11,” within each PDF
- Facilities and administrative (F&A) costs should be 8 percent of your total direct costs, less equipment
- Comply with federal/NIH policies on human subjects, animals and biohazards
- Comply with federal/NIH biosafety and biosecurity regulations



### **REMEMBER:**

The primary PI is responsible for all communications, for assembling the application materials and for coordinating progress reports.

## Applications With Multiple PIs

If your project has multiple PIs, one of you must be the primary NIH contact. This person is responsible for all communication, for assembling the application materials and for coordinating progress reports. At the same time, this PI may not have other special roles or responsibilities within the project team.

The contact’s information should be entered on the SF424 (R&R) cover component. All other PIs should be listed in the research and related senior/key person component as PIs. The commons (login) ID of each PI must be included in the credential field of the research and related senior/key person component. If it is not, NIH will reject the application.

You must also include a multiple PI leadership plan. The plan should describe your rationale for having more than one PI as well as the leadership team’s organizational structure. You should detail communication plans, the decision-making process for scientific direction and procedures for resolving conflicts. If you have planned budget allocation, you should describe how resources will be distributed to the project’s specific components or individual PIs.

END OF CHAPTER 7 PREVIEW

## Chapter 8: The NIH Application Review Process

This chapter outlines the National Institutes of Health's (NIH) review process. It describes how the Center for Scientific Review assesses applications and assigns them to review groups. It also explains how your application moves from an integrated review group (IRG) to a scientific review group (SRG) to an institute or center's advisory board or council.

You'll learn the four steps of the initial peer review process and how an SRG (otherwise known as a study section) rates your application. We describe how five criteria — Significance, Innovation, Approach, Investigators and Environment — are used to score your proposal. We explain the importance of Overall Impact, what percentiles mean, and how to interpret summary statements.

Also included in this chapter is information on tracking your application and steps to take once you've received a response from NIH. You'll learn about just-in-time information and how to resubmit your application if it is not funded the first time around.

## NIH REVIEW PROCESS: A BRIEF OVERVIEW

Once you have submitted your application to NIH, it goes through a few levels of review. First, the Center for Scientific Review performs a cursory assessment, checking for errors that automatically disqualify an application.

If there are no errors, the center sends your proposal to the group of reviewers known as the IRG. From there, your application goes to a study section (SRG).

The SRG is composed of roughly 20 scientists, mostly non-federal, who have expertise in relevant disciplines and current research areas. The scientific review officer (SRO), who is an NIH staff member, leads this group and appoints a few key reviewers to analyze your proposal in detail. The remaining members scan your application, reading only certain sections in depth.

The study section votes and scores your application on the five review criteria: Significance, Innovation, Approach, Investigator(s) and Environment. The group also evaluates your project's Overall Impact. The SRO compiles a summary statement that includes your application's scores as well as a more detailed critique.

After the SRG's assessment, your application goes to institute/center national advisory councils for review. Councils are composed of both scientists and lay members chosen for their expertise and activity relating to health and disease. Your application is only eligible for funding if both the study section and the institute/center advisory council recommend it.

## NIH CHECKS YOUR APPLICATION

As soon as NIH receives your proposal, it goes to the Center for Scientific Review for a cursory review. The staff there makes sure it conforms with administrative and formatting requirements.

NIH calls this check a potential failure point because the agency may return your application without a peer review. This would happen if you:

- Didn't list other support
- Failed to include sufficient human or animal documentation, data, assurances, or other required documentation
- Omitted pre-approval documentation for submitting an application requesting \$500,000 or more in direct costs for any one year
- Left out pre-approval documentation for an investigator-initiated clinical trial
- Didn't show documentation of approval for using select agents
- Included a detailed budget when it should have been a modular one
- Improperly formatted your application (wrong font size and margins)
- Submitted the forms in the wrong way — for example, emailing them instead of submitting through grants.gov
- Didn't meet the requirements of a request for applications or institute-specific program announcement, if responding to one of the initiatives
- Contacted a reviewer
- Submitted your application late.

## YOUR APPLICATION GETS AN NIH ID NUMBER

The Center for Scientific Review gives your application a unique identification number that looks like this: 1 R01 AI183723 02 A1 S1. Each part of the identifier provides a snippet of information about your application.

- The first number is the application type; for example, a new application is Type 1. This tells NIH whether your application is a new, renewal, noncompeting or other type of application.
- Next is the activity code, or the type of grant you've applied for; in your case, an R01 research grant.
- The next two-letter abbreviation is the institute code. For example, the National Institute of Allergies and Infectious Diseases code is AI.
- Next is the unique serial number Center for Scientific Review assigns.
- Then comes the suffix showing the support year for the grant.
- The final two are codes for a resubmission, supplement or fellowship institutional allowance.

In the eRA Commons, the website where you submit your application (<https://commons.era.nih.gov/commons/>), you'll see this NIH number. You'll also see the old grants.gov tracking number. But NIH staff will typically refer to your application using the NIH number.

## About the Consulting Editor — Dorothy E. Lewis, PhD

Dr. Lewis has had continuous NIH funding since 1985, experiencing both times of multiple grants and reduced funding. She is a member of the AIDS Immunology and Pathogenesis study section (2007-2011) and became chair in 2009. She is thus very familiar with the new NIH application system and new methods of review, which focus greatly on impact. She has more than 140 publications, a few book chapters and reviews. And she has mentored many graduate students, fellows and other faculty members in grant writing, both in a formal course on the subject in the 90s, and then as the chair of the mentoring committee for the Center for AIDS (BCM/UTHEALTH), which was recently renewed in its fourth cycle.

Currently, Dr. Lewis is supported by NIH via an R37 that examines T cell dysfunction in HIV patients, the abovementioned CFAR as the Immunology core director, and a grant that examines how HIV might affect fat differentiation with a colleague at BCM. She is also supported by Novartis to develop a method to enrich fetal DNA from the maternal circulation for the purpose on noninvasive genetic diagnosis. She teaches medical students and graduate students at UTHEALTH and mentors various predoctoral and postdoctoral candidates, including in fellowship and grant writing.

Dr. Lewis received her PhD in Microbiology in 1978 from the University of Arizona in Tucson. She then did an NIH-supported postdoctoral fellowship at the University of New Mexico School of Medicine in Albuquerque under the mentorship of Dr. Noel Warner. She worked on an autoimmune model in mice trying to determine which immunologic abnormalities were genetically associated.

She became acquainted with flow cytometry during her fellowship and used instruments in Los Alamos to characterize murine T and B cells.

She was on a chartered study section from 1992-1996 and then participated in multiple review panels related to HIV or flow cytometry in the 1990s. She served on the NIAID council from 2002-2006 on the DAIDS subcommittee, which exposed her to policy matters and how topics are chosen by program.