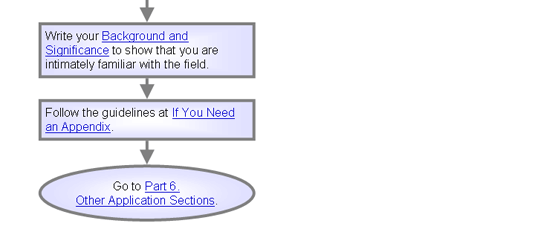
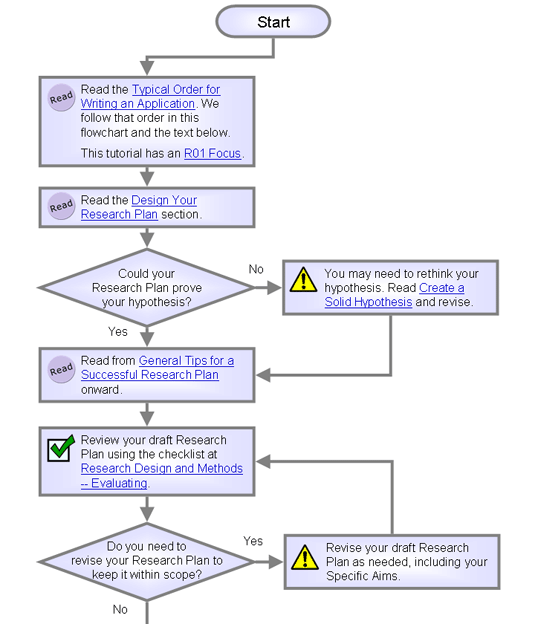
Source: NIH Grantwriting Cycle: <http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a1>

**Part 5. Research Plan**

|  |  |
| --- | --- |
| [[Logo and Link to Index: NIH Grant Cycle](http://www.niaid.nih.gov/ncn/grants/cycle/default.htm)](http://www.niaid.nih.gov/ncn/grants/cycle/default.htm) | [**<< previous**](http://www.niaid.nih.gov/ncn/grants/cycle/part04.htm)**·**[**NIH Grant Cycle**](http://www.niaid.nih.gov/ncn/grants/cycle/default.htm)**·**[**next >>**](http://www.niaid.nih.gov/ncn/grants/cycle/part06.htm) |
| Help us improve our outreach to you by emailing [deaweb@niaid.nih.gov](mailto:deaweb@niaid.nih.gov). |



**Table of Contents**

* [Are You Ready for This Part?](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#ready)
* [Typical Order for Writing an Application](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#aa)
  + [R01 Focus](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#aa1)
* [Design Your Research Plan](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a1)
  + [General Tips for a Successful Research Plan](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a1c)
  + [Reference Publications](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a1b)
  + [Start With Specific Aims](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a2)
  + [Preliminary Studies/Progress Report](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a4)
  + [Research Design and Methods -- Writing](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a5)
  + [Keep Track of People, Resources, and Timing](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a2a)
  + [Consider Special Requirements](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a6)
  + [If Your Application Has Multiple PIs](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a10)
  + [Consultants or Collaborators -- How They Differ](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a11)
  + [Where to Add Consortium and Contractual Information](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a12)
  + [What Resources Do You Need to Share?](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a13)
  + [Research Design and Methods -- Evaluating](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a6b)
  + [Background and Significance](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a3)
  + [If You Need an Appendix](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a14)

**Are You Ready for This Part?**

[Part 5. Research Plan](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm) tells you how to write the Research Plan section of your application and integrate all the parts into a consistent whole as the design evolves.

Before reading this page, be sure that you . . .

* Know how to use this tutorial and where to find tools. Read [How to Use the NIH Grant Cycle](http://www.niaid.nih.gov/ncn/grants/cycle/part00.htm#a2) in [Start Here](http://www.niaid.nih.gov/ncn/grants/cycle/part00.htm). Find helpful [Tools](http://www.niaid.nih.gov/ncn/grants/default.htm#tools): application samples, checklists, timelines, and contacts.
* Have picked a topic, hypothesis, and award type. Read [Part 2. Game Plan](http://www.niaid.nih.gov/ncn/grants/cycle/part02.htm) to learn how to create a strategy for your research, including timing and choosing a topic and an award type.
* Know whether your application will be investigator-initiated, or you will respond to a request for applications; understand funding opportunity announcements. Read [Part 2. Game Plan](http://www.niaid.nih.gov/ncn/grants/cycle/part03.htm).
* Know how to scale the research scope and design a project, including resources, effort, special requirements, and collaborators -- read [Part 3. Define Your Project](http://www.niaid.nih.gov/ncn/grants/cycle/part03.htm).
* Understand how to appeal to reviewers. Know how to write to your audience, make reviewers want to read your application, and avoid problems in review. Read [Part 4. Target Your Audience](http://www.niaid.nih.gov/ncn/grants/cycle/part04.htm).
* Understand NIH peer review. You'll need this knowledge to write your application. See [Part 8. Assignment and Review](http://www.niaid.nih.gov/ncn/grants/cycle/part08.htm).

**Typical Order for Writing an Application**

After the planning stage, the actual writing of an R01 application is a major undertaking that entails its own strategy. It is important to understand [Part 4. Target Your Audience](http://www.niaid.nih.gov/ncn/grants/cycle/part04.htm) before reading this section.

Below we suggest an order for writing the application sections and show you how to deal with your evolving design.

|  |  |
| --- | --- |
| |  | | --- | | This tutorial does not replace the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm). | |

Graphic: star.**Our Advice: Think of Each Section as Part of an Integrated Whole**

Use the following order and approach:

1. Write the draft of your Specific Aims section of the Research Plan.
2. Write the Research Design and Methods section of the Research Plan, considering the personnel and skills needed for each step.
3. Evaluate your Specific Aims and methods and how they affect your budget.
4. As your writing progresses, reevaluate and revise your hypothesis and Specific Aims.
5. Last, prepare your Abstract and title.

As you design your project, you should adjust other application sections to keep it all on track.

For example, evaluate the impact of the Specific Aims, methods, personnel, and other sections you are developing so you can keep your budget at an appropriate level for your career stage and goals.

You should also design your experiments with an eye on the time needed to perform them, allowing for the fact that research usually takes longer than people think.

If you decide to prepare your application in a different order, you can still find helpful advice and information here. Use the [Table of Contents](http://www.niaid.nih.gov/ncn/grants/cycle/part06.htm#toc) above or the Find command of your Web browser to search this page.

**R01 Focus**

This tutorial is geared especially toward investigators seeking an R01, the basic NIH grant. It does not replace the detailed instructions in the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm). NIH changes these instructions frequently, so download a fresh copy for each application.

You will apply electronically for any R-series grant, including the R01. Read more at [Get Ready Now to Apply Electronically](http://www.niaid.nih.gov/ncn/grants/cycle/part02.htm#f).

**Design Your Research Plan**

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| --- | --- |
| |  | | --- | | Design your research to answer the question posed by your hypothesis. | |

Your Research Plan describes what you are proposing to do, why the research is important, and how you will carry it out.

Because it is the core of your application, a top-quality Research Plan is critical to your funding success.

**Graphic: star.Our Advice: Convince Reviewers of Five Key Points**

Design your research to answer the question posed by your hypothesis -- see [Create a Solid Hypothesis](http://www.niaid.nih.gov/ncn/grants/cycle/part02.htm#e). Throughout the Research Plan, give enough detail to convince reviewers of the following:

* Your hypothesis is sound and important.
* Your Specific Aims are logical and feasible.
* You understand potential problems.
* You can analyze the data.
* You are the ideal candidate to perform this research.

**Research Plan Structure**

The Research Plan has four main parts, sections 2 to 5 in the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm):

* Specific Aims: goals of the research you intend to conduct
* Background and Significance: importance of the research to science and public health
* Preliminary Studies/Progress Report: data showing the viability of your proposal
* Research Design and Methods: detailed description of your planned experiments

You can find a completed outstanding [Research Plan](http://www.niaid.nih.gov/ncn/grants/app/default.htm#rpindex) from a first-time investigator at [Sample R01 Applications and Summary Statements](http://www.niaid.nih.gov/ncn/grants/app/default.htm).

Your funding opportunity announcement gives you detailed requirements. For example, you'll need to follow page limits; e.g., the 25-page limit for R01s applies to the sections listed above. (Note that starting in 2010 Research Plans will be 12 pages for R01 applications, and NIH will reduce the length for other grant types as well.)

Write your Research Plan in a word processor using the PHS 398 Research Plan form in the Grant Application Package.

Here's how to create and assemble your Research Plan attachments to meet the page limit. See NIH's [Page Limitations](http://era.nih.gov/ElectronicReceipt/faq_prepare_app.htm#2f) for more details.

From a single document, create separate PDF attachments for each Research Plan section.

* Don't worry if this move increases the size by a few pages -- white space doesn't count.
* Later, you may get a validation warning message to that effect. As long as your original Plan was 25 pages or less before separating the sections, don't be concerned. NIH staff also check the application.

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| Image: Decision Point. | **Can you design your research to answer the question posed by your hypothesis?**   * **No.** You may need to rethink your hypothesis. Read [Create a Solid Hypothesis](http://www.niaid.nih.gov/ncn/grants/cycle/part02.htm#e), then return here to continue reading. * **Yes.** Continue reading. |

**General Tips for a Successful Research Plan**

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| --- | --- |
| |  | | --- | | Don't put anything in your Research Plan that you don't plan to do! | |

**Graphic: star.Our Advice: Think About Streamlining, Graphics, References, and More**

Here are some pointers for creating a top-notch Research Plan:

* **Streamline.** Don't put anything in your Research Plan that you don't plan to do! Keep it lean. The more you put in, the greater your chances of making a mistake.
* **Graphics.** Include graphics and timetables to illustrate the flow for your experiments and personnel.
  + Chart your experiments with decision trees showing alternative pathways should you get negative results.
  + Include these graphics in the application; they will help peer reviewers understand what you plan to do.
* **Confidential information.** Do not include confidential information unless you have submitted a patent application.
  + If you do include it, check "Yes" in the appropriate box on the Research and Related Other Project Information form.
  + To remind reviewers, mark proprietary information wherever it appears.
  + You can mark text throughout or establish a style for confidential materials. See the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm) for instructions.
    - Marking confidential materials can help protect your in case of a [Freedom of Information Act](http://www.usdoj.gov/oip/index.html) request.
    - It also reminds the reviewers that the material is confidential and that your research is special -- having confidential information is part of what makes you the ideal researcher for the project.
  + **Never include confidential information in the title or Abstract**. Those sections will become public if your grant is funded.
  + See the [Privacy, Conduct, Conflict of Interest, and Clinical Research Ethics](http://www.niaid.nih.gov/ncn/qa/ethics.htm) questions and answers.
* **No introduction for a new application.** An introduction is for a resubmission or revised application (administrative supplement) only.

**Reference Publications**

Throughout your Research Plan, reference all relevant literature for your concepts and methods. References show your breadth of knowledge of the field. If you leave out an important work, reviewers will assume you're not aware of it.

* Cite the scientific literature thoroughly but not excessively -- aim for fewer than 100 citations.
* Cite publications that are current and relevant to the project or show that you or your collaborators used your proposed methods.
* Check the list of reviewers, and be sure to include any of their publications that are relevant to your project.
* Refer to unpublished work, including information learned through personal contacts.
* In general, do not include a copy of publications anywhere in the application. Read more about rules for publications in [If You Need an Appendix](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a14).
* Make sure to list all citations in your [Other Project Information Form: Bibliography and References Cited](http://www.niaid.nih.gov/ncn/grants/cycle/part06.htm#b4a) section.

**Start With Specific Aims**

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| |  | | --- | | You will design experiments that support your Specific Aims, and aims that will answer the question posed by the hypothesis. | |

Your Specific Aims state what you plan to accomplish during the grant and are a good starting point for writing your Research Plan.

Do not confuse them with your long-term research goals, which you'll write later in [Background and Significance](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a3).

As you prepare your application, you will design experiments that support your Specific Aims, linking them to the Research Design and Methods section.

Choose Specific Aims peer reviewers can easily assess. Each one should be an achievable end point rather than a best effort. This section should be about one page.

You can find a completed outstanding [Specific Aims Attachment Sample](http://www.niaid.nih.gov/ncn/grants/app/default.htm#rpindex) from a first-time investigator at [Sample R01 Applications and Summary Statements](http://www.niaid.nih.gov/ncn/grants/app/default.htm).

**Graphic: star.Our Advice: Know the Purpose, Scope, and Audience**

* Your Specific Aims describe well-focused objectives and milestones.
* Your aims test your hypothesis.
* You should probably limit your proposal to three or four Specific Aims. For new applicants, being too ambitious is a common mistake.
* Have no more than one or two sets of experiments for each aim. If you need more, reorganize.
* Think of this section as an expanded table of contents for your methods.
  + List each Specific Aim as a bold header.
  + Under the header, list experiments you plan to accomplish, and briefly state how the aim will help prove your hypothesis.
* Write this section for all peer reviewers, the experts and non-experts in your field, since they will all read it. Use terms a broad audience can understand.
* Review and rewrite your draft Specific Aims as you work out the details of your Research Plan.
* If you are applying for more than one grant, make sure the Specific Aims differ.

**Preliminary Studies/Progress Report**

A new R01 application includes a section on preliminary studies. Your Specific Aims build on this foundation.

If you do not have preliminary data, read [Which Award Type Suits You Best?](http://www.niaid.nih.gov/ncn/grants/cycle/part02.htm#c)

If you are preparing a renewal or revision (competing supplement), go to the next section on progress reports.

**Preliminary Studies**

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| |  | | --- | | Reviewers use the preliminary studies section to assess your competence to do the work. | |

Reviewers use this section together with the biographical sketches to assess the investigator peer review criterion reflecting your competence to do the work.

**Graphic: star.Our Advice: Present Your Data, and Show You Know What They Mean**

By providing preliminary data, you build reviewer confidence that you can handle the technologies, understand the methods, and interpret results.

* Interpret preliminary results critically.
  + Give alternative meanings to the data to show you've thought the problem through and will be able to meet future challenges.
  + If you don't do this, the reviewers will!
* Include enough information to show you know what you're talking about.
  + The more complex the project, the more data you need.
  + Tell them how your early work prepared you for the new project.
* Though you may include other people's publications, focus on your preliminary data or unpublished data from your lab. When results are from other labs, make clear which data are yours and which are not.
* Include previous experience that shows you can direct the proposed research and achieve its aims.
* You can find a completed outstanding [Preliminary Studies Attachment Sample](http://www.niaid.nih.gov/ncn/grants/app/default.htm#rpindex) from a first-time investigator at [Sample R01 Applications and Summary Statements](http://www.niaid.nih.gov/ncn/grants/app/default.htm).
* For tips for new investigators, go to [Are You "New"?](http://www.niaid.nih.gov/ncn/grants/new/new07.htm)

**Progress Reports**

If you are applying for a renewal or a revision (competing supplement), prepare a progress report instead of preliminary studies. Your progress report should include the following:

* Your grant project period beginning and end dates.
* A summary of the importance of your findings in relation to your Specific Aims.
* An account of published and unpublished results, highlighting your progress toward achieving your Specific Aims.

Find more information in [Part 12. Renewal Application](http://www.niaid.nih.gov/ncn/grants/cycle/part12.htm). To learn about revision applications, go to the [Revision of a Grant](http://www.niaid.nih.gov/ncn/sop/compsupp.htm) SOP.

**Research Design and Methods -- Writing**

Your Research Design and Methods is the heart of your Research Plan. It's a good idea to order this section by your Specific Aims. Enter a bold header for each Specific Aim.

Before starting, read [Plan and Organize Effectively](http://www.niaid.nih.gov/ncn/grants/cycle/part04.htm#d2) and [How NIH Review Criteria Affect Your Score](http://www.niaid.nih.gov/ncn/grants/cycle/part08.htm#f8).

You can find a completed outstanding [Research Design and Methods Attachment Sample](http://www.niaid.nih.gov/ncn/grants/app/res-design.pdf) from a first-time investigator at [Sample R01 Applications and Summary Statements](http://www.niaid.nih.gov/ncn/grants/app/default.htm).

**Graphic: star.Our Advice: Be Detailed, Provide a Timeline, and Use Consultants**

**Be Detailed**

|  |  |
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| |  | | --- | | Be detailed: for each Specific Aim, spell out what you propose to do, how long it will take, and what resources you will need. Reviewers want to know which viruses, cells, techniques, and more. | |

For each Specific Aim, spell out what you propose to do, how long it will take, and what resources you will need.

* Include the results you expect and their significance.
* Describe each method and experiment in detail.
* Give criteria for success.
* People or roles and staff hours needed.

Include graphs, images of gels, micrographs, and other items here, not the Appendix.

While you may assume reviewers are experts in the field and familiar with current methods, they will not make the same assumption about you.

It's not enough to state: "We will grow a variety of viruses in cells using standard *in vitro* tissue culture techniques."

Give details to show you understand and can handle the research.

* Peer reviewers want to know which viruses, cells, and techniques; the rationale for using a system; and exactly how the techniques will be used.
* Specify animal models, exposure times, reagents and how you will get them, statistical analysis methods, and other details. If a technique is well known, a citation is enough.
* If you have little published experience with a method, provide even more details.

Omit information not needed to state your case. Reviewers will look for flaws and penalize you heavily for them. Don't give them ammunition by including anything you don't need.

**Give a Timetable**

Reviewers appreciate having a timeline that shows how and when you will accomplish your Specific Aims, including any overlap of experiments and alternative paths.

Use flow charts and decision trees to show paths of experiments and how they progress, including alternatives -- what you will do if you get negative results. If you used graphics to plan the project, put them in the application.

**Use Consultants**

Consider relying on consultants to fill in needed expertise.

State how collaborators or consultants will fit into the project. Then list them as key personnel, and provide biosketches. For more information, go to [Consultants or Collaborators -- How They Differ](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a11) and subsequent pages.

**Keep Track of People, Resources, and Timing**

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| |  | | --- | | Plot out people or skill-based roles and staff hours needed for each task. | |

**Graphic: star.Our Advice: Note Who, What, and How Much Time**

As you design your experiments for your Research Design and Methods, keep a running tab of the following essential data on a separate piece of paper:

* **Who.** A list of people who will help you with your Key Personnel section later.
* **What.** A list of equipment and supplies for the experiments you plan.
* **Time.** Timing directly affects your budget as well as how many Specific Aims you can realistically achieve.

Having this information handy will help you finalize your budget justification and other sections later.

For each task, you will plot the people or skill-based roles and staff hours needed. Allow more time than you expect to need -- read more in [Think About Scope, Amount, and Effort](http://www.niaid.nih.gov/ncn/grants/cycle/part03.htm#a).

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| Image: Decision Point. | **Will your research have any special requirements such as human subjects, vertebrate animals, select agents, stem cells, or rDNA?**   * **No.** Skip ahead to [If Your Application Has Multiple PIs](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a10). * **Yes.** Continue reading here. |

**Consider Special Requirements**

As you draft your Research Plan, remember that some areas of research have special requirements: human subjects, vertebrate animals, select agents, stem cells, and rDNA.

If your research is in one of these categories, read [Will Your Research Have Special Requirements?](http://www.niaid.nih.gov/ncn/grants/cycle/part03.htm#b)

You may also want to review Section III of the [SF 424 R&R Application Guide](http://grants.nih.gov/grants/funding/424/index.htm) to learn which assurances your institution must file before we can award a grant.

Find more information online:

* [Biodefense and Biosecurity](http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm) portal
* [Human Subjects Resources](http://www.niaid.nih.gov/ncn/clinical/default_human.htm) portal
  + [How to Write a Human Subjects Grant Application](http://www.niaid.nih.gov/ncn/clinical/humansubjects/default.htm) tutorial
* [Animals in Research](http://www.niaid.nih.gov/ncn/clinical/default_animal.htm) portal
  + [How to Write an Application Involving Research Animals](http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutorial/index.htm) tutorial

**If Your Application Has Multiple PIs**

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| --- | --- |
| |  | | --- | | Your multiple PI leadership plan will affect your priority score. | |

**Graphic: star.Our Advice: Consider These Points About Multiple PI Applications**

Before you decide to be part of a multiple PI application, read [Take Heed -- You Might Want to Avoid a Multiple PI Application](http://www.niaid.nih.gov/ncn/grants/cycle/part03.htm#c2).

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| Image: Decision Point. | **Will you be part of a multiple PI application?**   * **No.** Skip ahead to [Consultants or Collaborators -- How They Differ](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a11) * **Yes.** Continue reading. |

**PI Roles**

Each PI must have a leadership role. The application should state which PIs are responsible for which Specific Aims.

* The science determines the level of effort for the PIs; there is no minimum level.
* One PI serves as contact PI, coordinating communication between all PIs and NIH and coordinating the progress report.
  + He or she must be affiliated with (not necessarily employed by) the applicant institution.
  + On large studies, other PIs may perform other coordination activities.
* All PIs have the same status and are responsible for their projects.

**Leadership Plan**

The leadership plan will affect your priority score. Peer reviewers judge its scientific merit and whether it promotes enough coordination and communication among PIs. Be thorough. It has no page limit and does not count toward the Research Plan page limit.

You must include a Multiple PI Leadership Plan that addresses these items:

* Rationale and justification for choosing the multiple PI approach.
* Administrative and scientific responsibilities for each PI, including who will be the contact PI. As in the Research Plan, state which PI is responsible for which Specific Aims.
* Governance and organizational structure of the team.
* Procedures for resolving conflicts.
* Policies for communication, data sharing, publication, and intellectual property.
* Budget issues.
  + Describe the process for making decisions on scientific direction and allocating resources and funds.
  + If they wish, the PIs may request that a budget allocation be included in the Notice of Award.
  + If each PI will have a budget, state how resources will be distributed.
  + If the PIs are in different institutions, NIH now uses a subaward arrangement, which may change.
  + Having more than one PI should not increase the cost of the application, except for items such as travel to scientific meetings.
  + If requesting money for administrative activities, put it in the leadership plan.

[eRA Commons](https://commons.era.nih.gov/commons/) will reject the application if the plan is missing. For more on what to include and how to present the information, see [Examples of Project Leadership Plans for Multiple PI Grant Applications](http://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf).

**Filling Out the Forms**

* NIH does not have co-PIs. Do NOT check that box on the SF 424 (Cover Page) form.
* Include the [Commons](https://commons.era.nih.gov/commons/) ID for each PI in the "Credential, e.g. agency login" field on the Research and Related Senior/Key Person Profile form.
* Put only the contact PI's name and Commons ID on the SF 424 form. He or she must be affiliated with the applicant institution.

Read the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm) for additional instructions. Go to [NIH Multiple Principal Investigators](http://grants.nih.gov/grants/multi_pi/index.htm).

**Consultants or Collaborators -- How They Differ**

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| |  | | --- | | Collaborators play an active role in the research; consultants provide advice or services and may participate significantly in the research. | |

Consultants and collaborators are treated differently in some parts of your application. Sometimes people play both roles. Read more about their benefits at [Using Consultants and Collaborators](http://www.niaid.nih.gov/ncn/grants/cycle/part03.htm#c1).

Consultants usually provide advice or services. They may participate significantly in the research, but often they help fill in smaller gaps, for example, supplying software, making technical comments, or setting up equipment.

* They do not receive a salary from your grant but may receive a fee.
* When paying them, your institution issues a [Form 1099 Misc](http://www.irs.gov/pub/irs-pdf/f1099msc.pdf#search=%221099%20miscellaneous%20tax%22) to the [Internal Revenue Service](http://www.irs.gov).

Collaborators always play an active role in the research.

* They do not get a fee, but the grant may pay part of their salary in person months through a consortium agreement (also called a subaward).
* Collaborators get an IRS [Form W-2](http://www.irs.gov/pub/irs-pdf/fw2.pdf?portlet=3) from their institutions.

Ask your institution's business office or speak to your program officer for help deciding whether to use a subaward or consultant.

**Using subawards.** Subawards allow another organization to perform some activities for your grant under your supervision.

They enable collaborations between you -- the grantee -- and the subawardee. This arrangement does not involve not NIAID -- you are responsible for the actions of the subawardee.

Here is an example of when you would use a subaward. If you need to develop knockout mice for your research, you can hire a biotech company to do the work. The cost of producing the mice would be a in subcontract from your institution to the other organization.

Include the details of the mouse work in your application because the initial peer review committee will evaluate it.

**Managing subawards.** In managing subawards, grantees are fully responsible for the following:

* All actions of the subaward related to the award.
* All contact with NIAID.

As the grantee, you (not the subawardee) are accountable to NIAID for the performance of the research project, spending of grant funds by all parties, reporting requirements, negotiating animals in research and human subjects assurances, and all other obligations for the grant.

Keep the following in mind:

* You must play a substantive role in the research; you cannot just pass along funds to another institution.
* If we need information from your subawardees, we will contact you.
* If there's a problem with a subawardee, we will expect you to take care of it.
* You can add a subaward to your project anytime.

**Where to Add Consortium and Contractual Information**

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| --- | --- |
| |  | | --- | | Send your consultants a sample letter they can return to you with their signature. | |

Consortium and contractual arrangements appear in several parts of your application.

**Research Plan.** If you're working closely with an investigator from another institution, your institutions may need a formal agreement of the terms of the collaboration.

* You do not include the agreement itself in your application. You will send it later just-in-time.
* In the Consortium/Contractual Arrangements attachment in your Research Plan, briefly describe any of these arrangements, stating the roles of the people and organizations involved.
* You typically include a breakdown of costs, such as personnel and supplies, as well as facilities and administrative costs.

Graphic: star.**Our Advice: Get Help, Send a Sample Letter**

Ask your institution's grant office to help you determine whether you need the consortium or other agreement described above.

You also need a letter from your consultants describing their willingness to participate in your project and their role.

* Send your consultants a sample letter they can return to you with their signature. That way, the letter will contain all the information you need, and they may return it to you faster.
* The letters go in the application. Attach as Letters of Support to the PHS 398 Research Plan form.

**Budget Form.** Make sure the information in the subaward budget form matches that in the Research Plan.

* Read the [Special Instructions for Preparing Applications with a Subaward/Consortium](http://grants.nih.gov/grants/funding/424/sf424_rr_guide_general_ver2.doc#Consortium) section of the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm) for details.
* You should enter the [subaward's](http://www.niaid.nih.gov/ncn/glossary/default6.htm#subaward) [DUNS](http://www.niaid.nih.gov/ncn/glossary/default2.htm#duns) number in the DUNS field in the subaward/consortium budget component. Even though NIH does not check for the number yet, it is considered to be required. If the subaward organization does not have a DUNS number when you're applying, enter nine zeros in that field.

**Biosketches.** Include all key personnel and other significant contributors listed in the application; attach a biosketch to the Research and Related Senior/Key Person Profile form.

For the consortium justification in a modular application, use the PHS 398 Modular Budget form in the Grant Application Package.

For nonmodular, use the R&R Subaward Budget in the Research and Related Budget components and read the [Special Instructions for Preparing Applications with a Subaward/Consortium](http://grants.nih.gov/grants/funding/424/sf424_rr_guide_general_ver2.doc#Consortium) section of the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm).

Also see [Create Your Budget](http://www.niaid.nih.gov/ncn/grants/cycle/part06.htm#b6c). For information about your responsibilities, go to the [Subawards (Consortium Agreements) for Grants](http://www.niaid.nih.gov/ncn/sop/subaward.htm) SOP.

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| Image: Decision Point. | **Will you create a new model organism, or are you requesting at least $500,000 in direct costs for any year?**   * **No.** Skip ahead to [If You Need an Appendix](http://www.niaid.nih.gov/ncn/grants/cycle/part05.htm#a14). * **Yes.** Continue reading. |

**What Resources Do You Need to Share?**

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| |  | | --- | | See if you need a sharing plan. Then read the linked documents for details. | |

Your application may need to include a plan for sharing model organisms, data, or genome-wide association studies.

If any of these requirements apply to your research, write your plan or plans as a single attachment.

All plans go in Section K in the Resource Sharing Plans section of the PHS 398 Research Plan form. They do not count toward the the Research Plan page limit.

To find out what to do, read the information below, which summarizes the main points from [NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources](http://grants.nih.gov/grants/sharing.htm).

**Model Organism Sharing**

If you plan to create a new model organism, you need to submit a sharing plan.

* First, review [Model Organisms for Biomedical Research](http://www.nih.gov/science/models/) for a list of organisms that require a plan.
* Include a justification if you plan to develop one of these organisms but are not providing a plan.
* For sample plans, go to [Where can I find basic information on sharing model organisms?](http://www.niaid.nih.gov/ncn/qa/sharingorg.htm#mbasic)
* Add information to other sections of the application as appropriate.
* For more information, see the following:
  + [Sharing Model Organisms](http://www.niaid.nih.gov/ncn/sop/shareorg.htm) SOP and [Sharing Model Organisms](http://www.niaid.nih.gov/ncn/qa/sharingorg.htm) questions and answers.
  + NIH [Sharing of Model Organisms FAQs](http://grants.nih.gov/grants/policy/model_organism/model_organisms_faqs.htm) at [NIH Model Organisms for Biomedical Research](http://www.nih.gov/science/models) and examples of plans at [NIH Model Organism Sharing Policy](http://grants.nih.gov/grants/policy/model_organism/index.htm).

**Data Sharing**

A data sharing plan is required only for applications requesting $500,000 or more in direct costs for any year unless otherwise specified in the funding opportunity announcement.

* Include a justification if you are requesting that amount and are not providing a plan. (You will also need NIAID's approval to submit an investigator-initiated application requesting that level of funding and document the approval in your cover letter. For details, see the [Big Grants](http://www.niaid.nih.gov/ncn/sop/biggrants.htm) SOP.)
* Your plan should state how you will share the final data set, without identifiers, through your institution no later than the time the main findings are accepted for publication. For a sample plan, go to our [Sample Data Sharing Plan](http://www.niaid.nih.gov/ncn/tool/datasharingex.htm).
* You may request funds to prepare, document, and archive data in your budget.
* Add information to other sections of the application as appropriate. NIH's [Data Sharing Policy and Implementation Guidance](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm) tells you how a data sharing plan may affect other parts of the application.
* For more information, read the following:
  + [Data Sharing for Grants: Final Research Data](http://www.niaid.nih.gov/ncn/sop/datasharing.htm) SOP and [Sharing Data](http://www.niaid.nih.gov/ncn/qa/sharingdata.htm) questions and answers.
  + NIH [Data Sharing FAQ](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm) at [NIH Data Sharing Policy](http://grants.nih.gov/grants/policy/data_sharing/index.htm).

**Data Sharing for Genome-Wide Association Studies**

Follow NIH's requirements whether you are proposing to conduct a genome-wide association study (GWAS) or simply planning to access the data in the NIH repository.

If you plan only to access GWAS data, you must state that in your cover letter. No plan is needed.

If you are proposing research NIH considers to be a GWAS, you'll need a plan, separate from your data sharing plan, for any award amount. You will also state in your cover letter that you are proposing to conduct GWAS research.

* NIH defines a GWAS as a study that looks at variation across the human genome to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.
* Your GWAS data sharing plan will describe how you will send your data to the [Database of Genotype and Phenotype (dbGaP)](http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap) or explain why that is not possible.
* Your IRB must approve your plan.
* NIH will check your application to make sure you included a plan and flag it for reviewers, who will assess the plan's adequacy.
* For sample plans, see NIH's [Guidance for Developing Data-sharing Plans for GWAS](http://grants.nih.gov/grants/gwas/gwas_data_sharing_plan.pdf).

For more information, see the following:

* [Data Sharing for Grants: Genome-Wide Association Studies](http://www.niaid.nih.gov/ncn/sop/gwas.htm) SOP.
* [Sharing Data](http://www.niaid.nih.gov/ncn/qa/sharingdata.htm) questions and answers.
* NIH's [Genome-Wide Association Studies](http://grants.nih.gov/grants/gwas/index.htm).

**Research Design and Methods -- Evaluating**

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| |  | | --- | | Did you describe limitations to your approach and how they may affect results and data? Did you call attention to potential difficulties and propose alternatives? | |

**Graphic: star.Our Advice: Ask Yourself Some Key Questions**

At this point, assess your Research Plan to make sure it is on track.

You may need to revise your draft, including your Specific Aims, to keep your project within your targeted range of dollars and time for your grant type, career stage, and research goals.

Do your assessment by answering the following questions:

* Do your Specific Aims address the hypothesis?
* Is the order of the Specific Aims and experiments appropriate?
* Did you give details, but omit anything not essential?
* Did you justify a highly innovative proposal?
* Is the approach feasible?
  + Did you convince reviewers you chose the right methods?
  + Did you describe how you will gain access to reagents or equipment? If collaborators will provide them, did you include letters of support describing their agreements with you, including their role on the project?
  + Are the procedures within your competence?
  + Did you propose a realistic level of work for the allotted time? Did you estimate how much you expect to accomplish each year and state any delays you can anticipate?
* Did you defend the choice of study design; did you state expected results and how they would support continuing the project?
* Did you describe limitations to your approach and how they may affect results and data? Did you call attention to potential difficulties and propose alternatives?
* If using animals or human subjects, did you include all the necessary details?
* If using hazardous materials, did you note the special facilities you can access for protecting the environment and staff?
  + Did you describe the precautions you will take in handling the materials?
  + Did you describe the training people involved have had in safe practices?
* If using select agents, did you complete the Select Agent Research attachment to the PHS 398 Research Plan?
* Did you show that you know how to handle results?
  + Did you define the criteria for evaluating success or failure of each experiment?
  + Will the experiments yield statistically significant results?
  + Did you include a statistical analysis to impress reviewers?
  + Did you describe your statistical methods for analyzing data you plan to collect?
    - Did you provide enough information -- methods of data analysis, power calculations, and justification for proposed sample size -- that peer reviewers can evaluate your approach?
    - Did you hire a statistician early on to advise you on sample sizes and the amount of data you'll need to collect?
  + Did you include well-designed tables and figures that have accurate and informative titles to meet reviewers' expectations for supporting data?
    - Did you label the axes and include legends so reviewers won't find discrepancies between your data and text?
    - Did you check and double check your data to avoid glitches?
  + Did you show you are aware of the limits to -- and value of -- the results you can expect based on current knowledge?
    - Did you state the conditions under which your data would support or contradict your hypothesis and your limits for interpreting results?

**Background and Significance**

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| --- | --- |
| |  | | --- | | Show that you are uniquely qualified to do the research. | |

Background and Significance is one of the three sections all reviewers are likely to read, so write it in terms understandable to a broad audience.

Graphic: star.**Our advice.** Put the significance of your research in the context of the state of your field and your long-term research plans.

You may find it easiest to focus the Background and Significance section after you complete your Research Design and Methods.

NIH referral officers use this section to direct your application to an institute for possible funding. Your description of the impact of your research can influence that decision.

In Background and Significance, convey the significance of your research to 1) increasing scientific knowledge and 2) improving public health.

* Describe how your research will advance your field.
* Point out how your research will fill knowledge gaps. Show that you are aware of opportunities, gaps, roadblocks, and research being done.
* Tell reviewers how your work meets the NIH mission to improve health through science -- just moving science forward is not enough. They will judge the likelihood that your research can ultimately cure, treat, or prevent disease.
* Highlight the successes of your related grants.

**Graphic: star.Our Advice: Show That You're Qualified, and Have an Innovative Idea**

* Reveal that you are intimately familiar with the field and why you are uniquely qualified to do the research. Refer to all relevant literature. Put this application's Specific Aims in context as part of your long-term Research Plan.
* If you are responding to an institute-specific initiative, significance is already spelled out. You can copy some of the text you need from the announcement.
* Significance also relates to being innovative.
  + If your proposal is highly innovative, you'll need to make a very strong case for why you are challenging the existing paradigm and have data to support your innovative approach.
  + Innovation can be tricky; we cover this topic in [Don't Propose Too Much or Be Too Innovative](http://www.niaid.nih.gov/ncn/grants/cycle/part04.htm#b).
* You can find a completed outstanding [Background and Significance Attachment Sample](http://www.niaid.nih.gov/ncn/grants/app/bkg-sig.pdf) from a first-time investigator at [Sample R01 Applications and Summary Statements](http://www.niaid.nih.gov/ncn/grants/app/default.htm).

**If You Need an Appendix**

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| |  | | --- | | Less is more. The more nonessential information you give reviewers, the more they have to fault. | |

NIH limits the kinds of information you may put in an Appendix. Rules differ by grant type and funding opportunity announcement, so check yours carefully. R01s allow certain publications in the Appendix.

* In general, an Appendix may include an unlimited number of questionnaires, data collection instruments, clinical protocols, informed consent documents, and some publications -- see the sections below.
* **Graphic: star.Our advice.** As with other parts of the application, follow the maxim that less is more: the more nonessential information you give reviewers, the more material they have to fault.

**Limited Items**

* Your Appendix can include up to three of the following items:
  + Manuscripts or abstracts accepted for publication but not published.
  + Published manuscripts or abstracts that are not on a public Web site.
  + Patent materials relevant to the project.
* If a publication is public, always link to it, or include its [NIH PubMed Central](http://www.pubmedcentral.nih.gov/) identification number in the text. Don't put a copy in the Appendix or elsewhere.
* Never include a manuscript not accepted for publication.
* For multiproject applications, each project or core may include up to three of the above items. See NIAID's [Instructions for Preparing a Multiproject Grant Application](http://www.niaid.nih.gov/ncn/grants/multi/index.htm).

**Images**

* Put images in the Research Plan attachments, not the Appendix. Follow the [Grant Application Guide](http://grants.nih.gov/grants/funding/424/index.htm) for size and resolution information.

**Submission**

* Send your Appendix electronically. Use the Appendix attachment of the PHS 398 Research Plan form in the Grant Application Package.
* If you can't submit materials electronically, contact your scientific review officer