Grant Training Center

National Institutes of Health

PROFESSIONAL GRANT DEVELOPMENT WORKSHOP

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Overview

Writing/Designing NIH Proposals

Grant Training Center has been educating for winning grants since 2004. Since then, we have helped thousands of people to navigate the complex and dynamic world of grant writing. This workshop is geared to help you learn how to match your proposal to the guidelines of donor agencies, and to write award-winning grants that will fund your projects.

You will learn about the world of grant procurement, be able to identify the key sections of successful proposals, and know how to demonstrate that your project exhibits the excellence and innovation that will land it on the short list. The diversity of the funding community, common stumbling blocks, and responses to various donor guidelines are all topics that will be covered in depth.

During the workshop, we will break down the strategic plan of grant writing including, but not limited to: needs statement, mission, goal, objectives, activities, evaluation, key personnel, and budgets. Each day our instructor will engage you in interactive exercises, writing, and discussions that will ensure you leave the class understanding how to research, write, and develop your specific project.

The text before you is one tool we will use to help you. The book has two primary functions: the first is to provide a series of worksheets specific to the type of grant you will be writing. The second function is to provide a step-by-step process for you to follow after the workshop is over. Please fill out these worksheets as the instructor asks; you will find that a written record will assist you in future proposal-writing endeavors. We hope that our text and worksheets will provide a series of guideposts to assist you when writing proposals long after this workshop has ended.

Overview

Workshop Goals

- Develop, prepare, and write successful NIH grant proposals
- Research and identify appropriate funding sources other than the NIH

Walk-Away Knowledge

- Identify the key elements of a grant proposal
- Effectively communicate and write each subsection of the grant, including the following:
  - Cover Letter
  - Title Page
  - Table of Contents
  - Abstract
  - Statement of Significance
  - Goal
  - Hypothesis
  - Specific Aims
  - Research Design
  - Methodology
  - Timelines and Graphics
  - Baseline(s)
  - Personnel
  - Budget
  - Dissemination
  - Sustainability
  - Supporting Documentation
- Understand how to approach and write for the NIH and appropriate foundations
- Ensure an institutional buy-in for your project
- Know how to package a proposal and receive feedback from donors

Workshop Outcomes

- Understand the grant review process
- Learn to submit proposals in your area of interest
- An appreciation for effective teamwork and the benefits thereof
- Present your idea to a mock peer-review panel
- Leave with a full-content proposal outline or concept paper

Introduction

To The Grant Writing Process

Introductory Worksheet

This worksheet will guide you throughout the workshop. Your answers will evolve into an outline or concept paper, which will feed into your grant writing process.

Who are you, as a researcher?

What is your idea, problem, or question?

Why is your idea significant, important, or needed?

Who will fund your project?

What is the match between your project and the donor, mechanism, institute, or study session?

Who will benefit from the grant?

What is the ultimate purpose or outcome of your project?

How will your hypothesis be proven?

How will your specific aims be achieved?

Who will implement your project?

How will you know the project succeeded?

What is the timeline for your grant?

How much time do you need to distribute the grant monies?

How will your project results be disseminated?

Collaboration & Networking Worksheet

Being aware of connections and potential networking opportunities can make your grant writing process easier. This worksheet will help you delve into the internal and external politics of your organization. Once you have identified potential allies, you can adjust proposal planning to make the most of this knowledge.

How can you convert your expertise into a grant request and tell the donor that you need external funds?

What internal politics do you need to consider prior to beginning the grant request?

What might be some of the external politics you should consider prior, during and after submission?

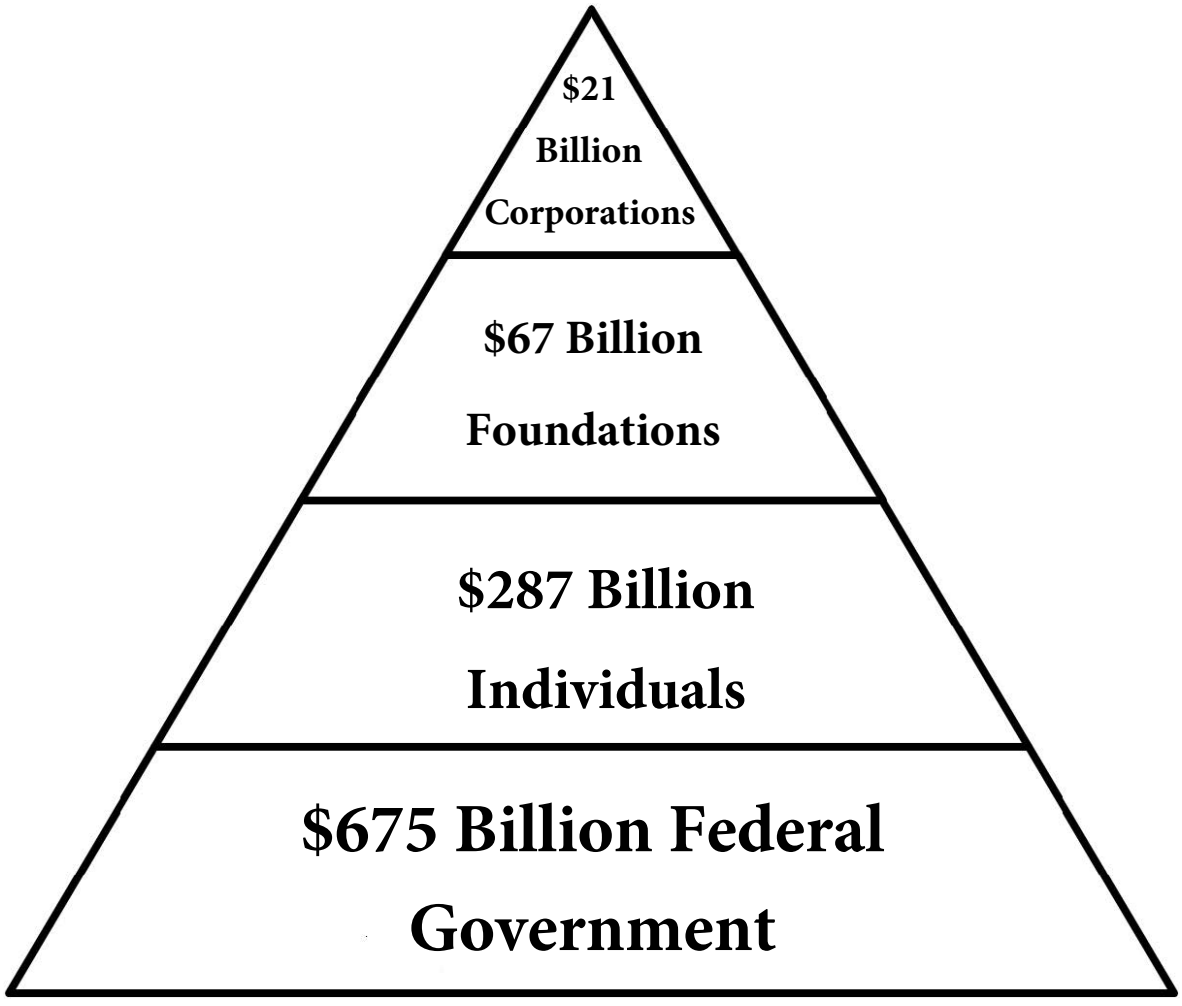
Who are some of the people you could recruit for your team or whose expertise would be helpful to seek?

Who else might be writing grants for the same funding as your team, and is it possible to combine teams or collaborate?

Where is the Money?

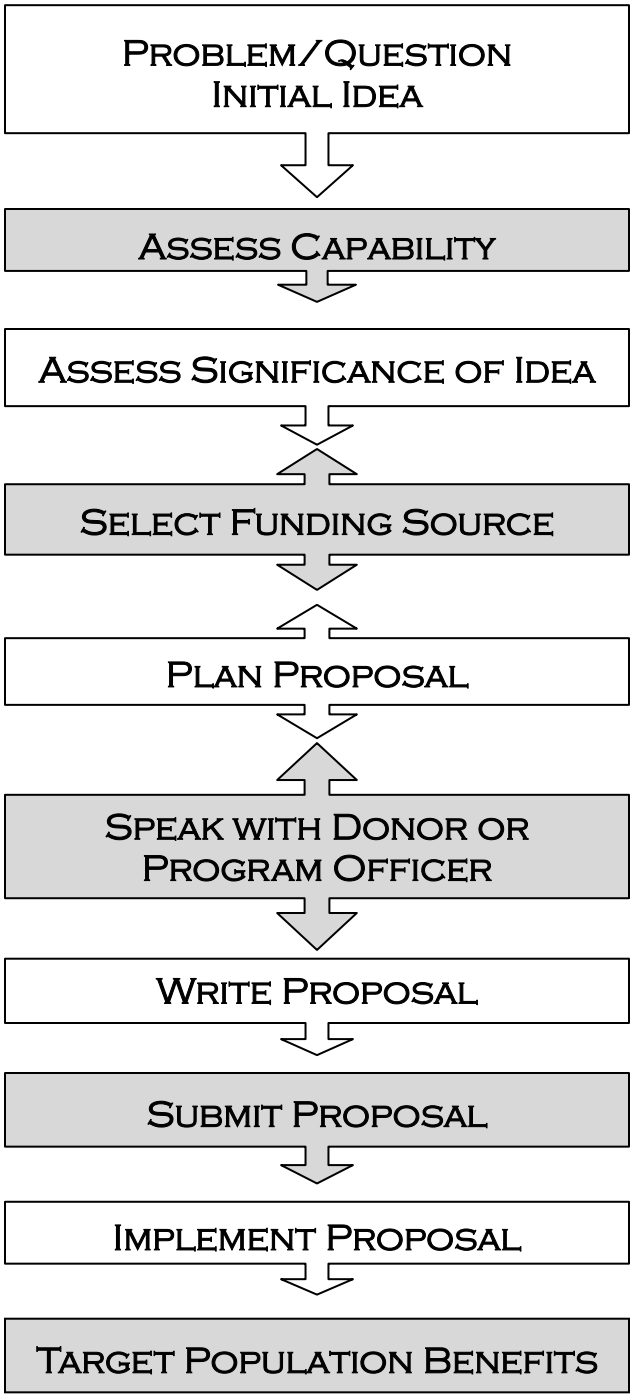
Now that you have collected some general information on the previous pages, we can turn our attention to the money. Securing funds for your project or experiment is the whole point of writing your proposal. Without the funding, your great idea will remain just that: an idea. So, what is your best chance of getting the award? Where is the money?

$1.050 Trillion Awarded in FY 2017



An estimated $1.050 trillion was awarded in 2017. Various Foundations & Corporations gave $88 billion in grants. Individual giving totaled $287 billion. By far, the largest donor was the Federal Government, which awarded $675 billion to grantees.

Grant Seeking Model



The diagram to the left can help you plan your writing process.

- Consider the problem or question you have in mind, an initial idea you may have talked over with colleagues, or the strategic plan of your organization.
- How will you assess your career path, including your current and future research? Your idea should be based on a thorough literature review and preliminary studies to date. The NIH encourages collaborative, cross-disciplinary, and translational research.
- How might you conduct a need-for-the-idea assessment to determine what other factors will play a role in your proposal? Do not forget to ensure a good match between your project and the funding institute.
- Selecting your institute or review panel, planning your proposal, and speaking with the donor or program officer may take a few iterations before you can begin writing your proposal in earnest. Do you have time allotted for these steps?
- After writing your proposal, have your colleagues, naïve readers, and an editor read it. Keep the necessary dates in mind to avoid any last-minute problems.
- How will you implement the project?
- Consider your target population and how they will benefit from the proposal.

4 Key Components

Expertise

You must start with a well-researched good idea. Investigating your idea will ensure that you are not reinventing the wheel, as well as providing you with an enriched background on the subject matter. What precedents exist that may help you gain support? What obstacles have others run into that may affect your idea?

Focus

Laying the groundwork to narrow the scope of your grant is the primary emphasis of this workshop. You will learn how to direct your or your team's energy into the proper channels for the best chance at submitting a winning proposal. The following diagram will help you generate a frame to accomplish this task.

Politics

Always a factor, the internal politics of your organization will be a key to gaining support for your idea. With regard to external politics, city and state officials can add support. Furthermore, you may have to consider any contenders for support within your organization. Are other people trying to get their ideas off the ground? Would it make sense to view them as partners instead of competitors? See the worksheet following the diagram for more details.

Strategic Planning

As the previous page illustrates, a request for funding is just one part of a larger scheme. To ensure the best chance for your proposal, the plan must be exhaustively fine-tuned with every point and its consequences considered. The diagram to the left will help you to craft an outline and a schedule that assists with and keeps you organized.

A poorly-packaged good idea will not get funded; a well-packaged mediocre idea will be successfully funded

Grant Writing Model

In conjunction with the Introductory Worksheet, this diagram will help you to focus on a single idea or problem at a time.

IDEA, PROBLEM, QUESTION

FUNDER	WHO WILL FUND YOUR PROJECT?
ORGANIZATION MISSION RESEARCHER	WHO ARE YOU, AND WHAT IS YOUR MISSION?
MATCH	IS THERE A MATCH BETWEEN YOU AND THE FUNDER?
STATEMENT OF SIGNIFICANCE	WHY DO YOU NEED THE MONEY?
HYPOTHESIS	WHAT IS THE ULTIMATE PURPOSE OR OUTCOME OF YOUR PROJECT?
SPECIFIC AIMS	HOW WILL THE HYPOTHESIS BE PROVEN?
METHODOLOGY	HOW WILL THE SPECIFIC AIMS BE ACHIEVED?
PERSONNEL	WHO WILL RUN THE PROJECT?
BASELINE	HOW WILL YOU KNOW YOU ARE SUCCESSFUL?
BUDGET	HOW MUCH WILL EACH ACTIVITY OF THE PROJECT COST?
DISSEMINATION	HOW WILL THE RESULTS OF THE PROJECT BE PUBLISHED OR OTHERWISE DISSEMINATED?
SUSTAINABILITY	HOW WILL THE PROJECT CONTINUE ONCE THE FUNDING CEASES?

Grant Seeking

For NIH Researchers

A Word about Funding Sources

One of the most important aspects of the proposal is getting the right fit between your project and the donor. While exploring the resources presented, keep the answers to the following questions at the front of your mind:

- **Which organizations should you research?**
- **Which types of grants would best support your project?**
- **Which types of grants would best support your project and your budget?**

To help you find answers to the questions above, we will turn to the USB issued to you. The links and sites on the USB represent a variety of organizations and agencies. While each of them awards grants or provides useful information, not all of them will be the right fit for your project. Your initiative and the objectives of your funder must be a good match. For example, you wouldn't research the National Institute of Allergies & Infectious Diseases as a funding source for your innovative and efficient double bypass procedure.

The resources contained on the USB and the following page are simply a guide to available grant-awarding resources. Once you are familiar with some of the NIH and foundations, you should conduct searches on your own to find the most appropriate funding for your project. Check with your library or institution's sponsored programs office for other helpful resources.

Some of the directories and registries on the following page will be helpful in your search. These organizations have online resources, some of which are free. However, some charge to use their online resource. Your library or institution may already have a login or other access code. Given the expense for a single resource, it is well worth your time to determine the resources already at your disposal.

Useful Websites

Check off the websites which may apply to your project. Research those you have marked for funding opportunities.

- ☐ **Federal Government** – Grants from all 26 agencies including, but not limited to: NIH, NSF, USDA,NASA, NOAA, EPA, US Department of Energy, and DoD.
- ☐ **National Institutes of Health**
- ☐ **Catalog of Federal Domestic Assistance**
- ☐ **Federal Register** – The latest information about the US government
- ☐ **Community of Science (COS/Pivot)** – All-inclusive search engine
- ☐ **European Commission** – A database for international funding
- ☐ **Foundation Center**
- ☐ **Graduate & Postdoctoral Extramural Support**
- ☐ **US National Library of Medicine**
- ☐ **Fundsnet Services** – Fundraising directory
- ☐ **InfoEd Global (SPIN)** – Research funding database
- ☐ **The Chronicle of Higher Education**
- ☐ **The Chronicle of Philanthropy**
- ☐ **PubMed**

Foundation Funding

Now that you have peeked into the world of Federal Government funding, we will take a look at a few other sources for funding. Foundations have the potential to be a good fit for your project. It's possible that your project or organization may be eligible for these kinds of grants. Every organization is different, and you may find that only one or two grants will be a good fit for your project. The point is gain the necessary funding to do your preliminary research. The descriptions of grant types below will assist you in finding prospective sources for funding, depending on the type of project you have in mind.

Common Types of Grants

General Purpose & Operating Support Grants

General Purpose

If your organization receives a general purpose grant, the money can be used to support the general expenses of your organization. Almost any expense – from new filing cabinets, to the printing of flyers, to the heating bill – is eligible. Receiving a general purpose grant means the funder supports your organization's overall mission, and trusts you to make good use of the money.

Operating Support

Receiving an operating grant means your organization can support the personnel expenses of operating your organization. Any individuals who need to be hired for the project can be paid with these funds. Winning an operating grant means the funder wants to support your personnel needs.

Program & Project Support Grants

Aside from general purpose or operating support grants, most other grants are some form of program or project support. Usually, a project grant is given to support a specific, connected set of activities, with a beginning and an end, explicit objectives, and a predetermined cost. The grant may be project-specific or restricted, and must be used for the directed purpose. In general, project grants are given to support projects related to the mission of the organization receiving the money. There are dozens of project grants. Here are some of the most common:

Planning Grants

If your organization is planning for a major new program, you may need to spend a good deal of time and money just figuring out how it will look as a finished product. Before you can even write a proposal to fund the new effort, you may want to research the needs of your constituents, consult with experts in the field, or conduct other planning activities. A planning grant supports this kind of initial project development work.

Seed Money or Start-Up Grants

A start-up grant helps a new organization or program in its first few years. The idea is to give the new effort a strong push forward, so that it can devote its energy right away to setting up programs without worrying constantly about raising money. Such grants are often for more than one year, and frequently will decrease in amount each year. For instance, a grant might be for $25,000 the first year, $15,000 the second year, and $7,000 the last year. The funder assumes that the new organization will begin to raise other funds to replace the decreasing start-up grant.

Management or Technical Assistance Grants

Unlike most project grants, a technical assistance grant does not directly support the mission-related activities of the organization. Instead, it supports the organization's management or administration – its fund raising, marketing, and financial management, and so on. This type of grant might help hire a marketing consultant, or pay the salary for a new fund-raiser position.

Facilities and Equipment Grants

Sometimes called "bricks-and-mortar" or capital grants, these grants help an organization buy or restore a long-lasting physical asset – a building, computer, or van, for instance. The applicant organization must make the case that the new acquisition will help it serve its clients better. Funders considering this type of request will not only be interested in the applicant's current activities and financial health, but will also ask about financial and program plans for the next several years. They want to be sure that if they help an organization move into a permanent space, for example, the organization will have the resources to manage and maintain it. No funder wants to help pay for a new building, only to have it close in four years because it is too expensive for the organization to maintain.

Endowment Grants

Some nonprofit organizations have set aside money for investing and earning interest. The organization spends only the interest and keeps the original sum, or principal, untouched. Such a fund is called an endowment and is commonly found within organizations with large physical plants, such as hospitals and colleges. Periodically, organizations launch fund-raising efforts to start or add to an endowment. Like facilities and equipment grant proposals, endowment requests will prompt funders to ask hard questions about the long-term financial outlook of the applicant. The funder wants to be sure that any gift to an endowment will stay with the principal earning interest, and not be drawn out to meet annual operating costs.

Program-Related Investments (PRIs)

In addition to grants, the IRS allows foundations to make loans – called program-related investments or PRIs – to nonprofits. PRIs must be used for projects that would be eligible for grant support. They are usually made at low interest, or even no interest. Unlike grants however, PRIs must be paid back to the grant maker. PRIs are often made to organizations involved in building projects.

Proposal Letters

Even if you know that one of the grants described is the perfect fit for your project, you will still have to convince the organization or individual that your idea is the best use of their resources. The best way to get your foot in the door is to write a Proposal Letter. Often this step is required by foundations, corporations, and individuals, and the quality of the letter can make or break your chances of winning the grant.

It may take as much thought and data-gathering to write an effective Proposal Letter as it does to prepare a full proposal. Don't assume that because it is only a letter, it isn't a time-consuming and challenging task. Every document you put in front of a funder says something about your agency; make sure your documents convey the right message. Each step you take with a funder should build a relationship for the future.

While most Proposal Letters should not exceed one page, a few exceptions may be made. For instance, if your organization has received funding from Foundation X, it may behoove you to take a couple of paragraphs to remind them how helpful their previous funding has been. To help you design a great and effective Proposal Letter, the components are detailed below.

Ask for the Gift

The letter should begin with a reference to your prior contact with the funder, if any. State why you are writing the letter, as well as how much funding is required from the particular foundation.

Describe the Need

In a very abbreviated manner, tell the funder why there is a need for this project, piece of equipment, etc. Remember, this letter helps the donor understand why they should grant your project the funding for which you are asking.

Explain What You Will Do

Just as you would in a fuller proposal, provide enough detail to pique the funder's interest. Describe precisely what will take place as a result of the grant. Donors who require this step will always want to know where their money and other resources will be directed.

Provide Agency Data

Help the funder know a bit more about your organization by including your organization's mission statement, a brief description of programs offered, the number of people served, and personnel data, if appropriate. Getting to know the details of your project will help the donor understand why their funding is necessary

Include Appropriate Budget Data

You can include half-page budget in your letter request, if some aspect of your financial planning is particularly compelling. Decide if this information should be incorporated into the letter or in a separate attachment. Whichever course you choose, be sure to indicate the total cost of the project. You should only discuss future funding if the absence of this information will raise questions.

Close

As with the longer proposal, a letter proposal needs a strong concluding statement. You must remind the donor of the highlights without beating them over the head with details.

Attach Any Additional Information

The funder may need much of the same information to back up a small request as a large one. Some items which you may find useful to include are as follows: a board list, a copy of your IRS determination letter, financial documentation, and brief resumes of key staff.

Medical Research Proposal Letter Example

January 9, 2015

Foundation representative, name of the foundation, address

Dear Mr. Alfred:

I am writing to inquire if the Bristol-Myers Squibb Foundation would consider a proposal from the Department of Cardiothoracic Surgery at New York University requesting a research grant of $150,000 per year for two years, to support our research project entitled “Calcific Aortic Stenosis: Mechanisms of Calcification and Development of Biological Markers.” The ultimate purpose of our research is to improve the clinical outcomes and quality of lives of patients suffering from cardiovascular diseases; this parallels the mission of Bristol-Myers Squibb Foundation to extend and enhance human life.

After hypertension and coronary artery disease, calcific aortic stenosis (AS) is third most common cardiovascular disease in the Western world. With a prevalence of 3-9%, calcific AS is also the most frequent valvular disease and the main cause for valve replacements in patients over the age of 60. Despite the high prevalence and mortality associated with calcific AS, there is no effective medical therapy for the disease and little is known about the molecular mechanisms driving its pathogenesis. The aim of our research is therefore twofold: (1) to identify proteins in patients with calcific AS that can be used to diagnose and monitor the progression of AS, and (2) to investigate the biological mechanism by which such proteins promote calcific AS so that we can identify possible therapeutic targets.

This research is a collaborative effort between clinicians within the Department of Cardiology and basic science researchers and surgeons with the Department of Cardiothoracic Surgery at New York University. This collaboration gives us the ability to comprehensively study the disease process of AS, from its initial diagnosis by Cardiologists to its ultimate treatment by Surgeons. The union of the clinical expertise from both Cardiologists and Surgeons with the analytical proficiency of Basic Scientists makes this an exciting and innovative project that will certainly increase our understanding of the pathogenesis of AS and hopefully serve to impact its future treatment.

The Department of Cardiothoracic Surgery at New York University Medical Center is an internationally recognized program performing over 1,200 open-heart operations per year. Through the partnership between our research and clinical divisions, our Department is uniquely poised at the forefront of cardiothoracic surgery as we have the capability to both, study the molecular basis of diseases and to apply the knowledge gained through research in the development of novel clinical therapies.

Thank you for your kind consideration of our project. I will be contacting you within the next three weeks for any feedback you may have. In the meantime, please do not hesitate to contact me if you desire additional information or if you have any questions. I look forward to talking with you soon.

Sincerely,

Lawrence B. Green, M.D., FACS, FACC
Professor of Cardiothoracic Surgery

Grant Seeking & NIH

The Process

You have a great idea for research that will change the world. Now what do you do? If your specialty falls under the biomedical category, your process will involve the following steps:

- **The RePORTER** – Always be sure no one else has had your idea!
- **PubMed** – Find and read articles by people who might decide the fate of your idea.
- **NIH Website**– Funding for your idea can only happen with an appropriate grant.

The RePORTER

If you are unfamiliar with the site, imagine a digital warehouse that contains records of all things related to NIH research since 1989. It is the query subsection of the larger Research Portfolio Online Reporting Tools (RePORT) site. General information and annual reports are the least of what this site has to offer. As a researcher, this site is the number one tool that sets you up for success. Press the link below to visit the RePORT homepage:

http://report.nih.gov/index.aspx

Once you have arrived, look for the small box in the bottom right of the screen. The box is a quick query form for the RePORT Expenditures and Results tool (RePORTER). You can do a fast search for a particular organization, individual, or institute. This is a useful function for those experienced with the site. If you want to conduct a more in-depth search, however, please click the link below:

http://projectreporter.nih.gov/

The page may look intimidating at first glance. At least twenty-eight choices with different sorting methods are scattered over the form. The thoughtful people at NIH have incorporated a helpful light blue circle with a question mark for every field. If you don't know what information you should enter, simply click on the blue circle for a brief explanation.

If you are new to the site, your best bet is to do a simple text search. Enter keywords for your research idea and click on the dark blue "Submit Query" button at the top of the form. Your results are sorted according to relevance, but you may sort by year, project number, or other criteria. The information readily visible includes the name of the project, the name of the Primary Investigator (PI), the fiscal year and the funding amount.

Each project has a checkbox. Check the boxes on a few of the projects that are closest to your research idea. At the top of the results, across from the heading of "Project Search Results," you will see three light blue buttons called: "Back to Query Form," "Save Query," and "Share Query." Under these buttons, you will see the word "Export." If you click on "Go," the projects you checked off will be exported to your computer. Exporting is a great alternative to attempting to recreate the same search you conducted at 2 a.m., which led you to the one project that seemed like a cornerstone to your research idea.

Once you have looked over the abstracts of several projects and have exported them safely to your computer, turn your attention to the PI listed for each. These are the people you may want as reviewers, or perhaps there are a few you may want to exclude for various reasons. Make a list of their names and their relevant projects in preparation for the next step in the process.

PubMed

If the RePORTER website is your number one tool for success, the PubMed site is surely your backup plan. Any journal article with ties to the biomedical world may be found here. Plase click the link below to visit the PubMed homepage:

http://www.ncbi.nlm.nih.gov/pubmed

At the top of the page, you will see a long search bar. If you enter keywords for your project, PubMed will dutifully produce a list of articles based upon relevance. However, you have already done the filtering of funded research. Use PubMed as a method to research the researchers. The list of PIs from the projects you exported earlier has now become a list of potential reviewers. A search of PubMed is the best way to find out the kind

of projects they have done, the types of successful research they have conducted, and their investigatory interests.

You may discover that the PI you wanted as a reviewer doesn't have the same amount of enthusiasm about your topic as you. You might find out that a PI has written so many articles about your research topic, it may be better to collaborate with him or her. The point is to find out this kind of information before you spend two months writing a proposal.

Reviewing the literature serves another purpose: enriching your knowledge base. As an example, you may have decided upon a particular methodology. Perhaps you read an article in which the PI discovered that a few adjustments to a similar methodology were necessary to make the project coalesce into something journal-worthy. Regardless, more knowledge is always a good thing when it comes to research.

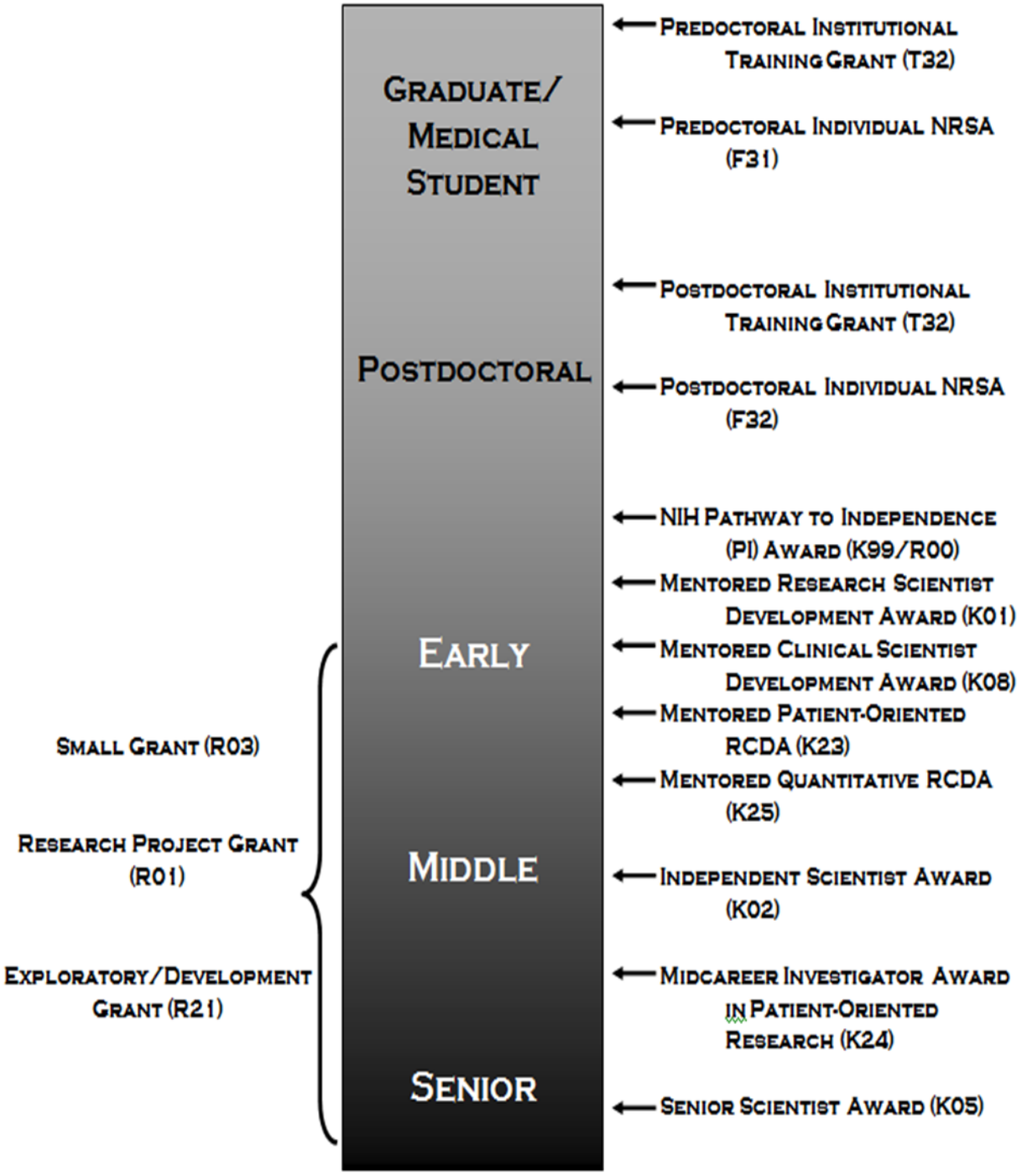
NIH Website

Having researched the RePORTER and PubMed sites, you are now ready to begin the search for an appropriate grant. For explanation of the various grant types, refer to the USB issued to you at the beginning of the workshop and explore the “National Institutes of Health (NIH)” section. Click on the link below to visit the NIH Funding page:

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

Contact the program officer of your organization to discuss the variety of grant types you feel are well-suited to your research. While speaking with the program officer, be sure to inquire about the money and time constraints of each grant discussed. You may find it helpful to contact the program officer to determine the institute’s enthusiasm about your research, advice on preparing an application, getting the right fit with the institutes and study sections, and for updates on your application status.

Contacting the more experienced researchers at your institution is a great method to get practical advice. Mentors are a necessity for new researchers, as they will help guide you through the process of obtaining an NIH grant. As a guideline for the types of grants you should consider at your current career level, please see the chart on the next page.


Graduate/ Medical Student
Postdoctoral
Early
Middle
Senior
Predoctoral Institutional Training Grant (T32)
Predoctoral Individual NRSA (F31)
Postdoctoral Institutional Training Grant (T32)
Postdoctoral Individual NRSA (F32)
NIH Pathway to Independence (PI) Award (K99/R00)
Mentored Research Scientist Development Award (K01)
Mentored Clinical Scientist Development Award (K08)
Mentored Patient-Oriented RCDA (K23)
Mentored Quantitative RCDA (K25)
Independent Scientist Award (K02)
Midcareer Investigator Award in Patient-Oriented Research (K24)
Senior Scientist Award (K05)
Small Grant (R03)
Research Project Grant (R01)
Exploratory/Development Grant (R21)

Examples of New Investigator Grants

New Investigators can expect four to five years of funding from the grants below, which should allow ample time to established a research career. Reviewers tend to have lower expectations in comparison to other grant options; they anticipate fewer preliminary data, resources, and publications. However, the data must support your research approach.

K08- Mentored Clinical Scientist Development Award

This grant is used to help mentor clinicians up to $150,000 as they transition from doctoral basic science and research to a research career. The research career development must be relevant to the institution's goals. The K08 award replaces the earlier K08, K11, K15, and K20 awards.

K99/R00 –Pathway to Independence Award

The primary purpose of the Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The program is designed to facilitate a timely transition from a mentored postdoctoral research position to a stable independent research position with independent NIH or other independent research support at an earlier stage than is currently the norm.

R15-Academic Research Enhancement Award (AREA)

This award is focused on small research projects conducted by faculty and students in health professional schools concentrating on biomedical and behavioral sciences limited to $300,000 over entire project period. Eligibility is determined at the time of application.

R21- Small Grant - Exploratory/ Developmental Research Grant

With this grant an investigator can request up to a total of $275,000 for the one to two years of exploratory research. New investigators have used this to conquer the preliminary studies requirement for the R01 grants even though it is designed for exploratory projects conducted by experienced investigators.

R03-Small Grant

An investigator can request up to $50,000 per year in direct costs. Preliminary data is not mandatory to apply for the R03 grant, meaning it supports a hypothesis project. However, according to the data collected by the NIAID, this grant does grant enough money to complete a research project, limited the preliminary data required for an R01 grant.

R01- Independent Research

This grant supports investigators with established preliminary data for three to five years. Reviewers prefer that your preliminary data has been published but, this is not a requirement.

Revision

How do you know when to revise your application and resubmit or when to begin over with a new idea? If reviewers thought your basic idea was interesting and important, the application may be worth revising. Upon revision, you may request that it be reviewed by the same study section.

Common fixable problems

- Poor writing.
- Insufficient information, experimental details, or preliminary data.
- Significance not convincingly stated.
- Approach not shown to be feasible, but you can demonstrate feasibility.
- Insufficient discussion of obstacles and alternative approaches.

Not fixable or more difficult problems

- Philosophical issues, or reviewers feel the work is not significant.
- Hypothesis not sound, or not supported by data presented.
- Work has already been done.
- Methods proposed were not suitable for testing the hypothesis.

Sometimes the problem lies with the SRG assignment. For example, suitable expertise may not have been available on the SRG, or the reviewers may have an unshakable and unreasonable belief that the your hypothesis is wrong. These circumstances occur much less often than commonly believed. If - after discussion with knowledgeable colleagues, including NIH program staff - you decide that a different study section would be more appropriate, revise the application and request review by a different SRG. Be sure to give reasons for your request (lack of reviewer expertise, lack of interest in the subject, differing philosophies, etc.)

It is usually better to revise and request a change of study section than to appeal and ask for a deferral for re-review. Often the appeal will be unsuccessful, if it appears to be based on a difference of scientific opinion. Moreover, even if deferral for re-review is granted, you will not be allowed to make any changes to the application. Even responses to any legitimate reviewer concerns in the original critique are not allowed, and these concerns may still prevent the application from receiving a fundable score. Furthermore, while the original application is undergoing reconsideration, a revised application cannot be submitted. Therefore, the opportunity to revise and resubmit will have been delayed by 4 months while the original application is still pending.

Revising Your Application

Read and reread the summary statement. Identify the concerns. Before you start revising, ask your Program Director to review your summary statement and give you advice. Also, ask someone in your institution who is experienced in grantsmanship and not involved in your proposed research to review your application, summary statement, and revision plans.

In the Introduction you should respond to the comments and suggestions of the reviewers. Address reviewers' comments point by point; you do not need to agree with all points, but you must address them. Use page numbers and other identifiers so reviewers can easily find where you have added new data or revised experimental approaches. A bar in the margin is a good way to show where revisions are. Highlight new sections with indenting, bracketing, underlining, or change of type. If you disagree with the reviewers, explain why and provide additional information if needed. However, an Introduction that is nothing but an angry rebuttal of the previous summary statement is unlikely to be well-received. Maintain as positive a tone as possible in the Introduction.

You are not guaranteed an award, even if you respond adequately to the criticisms in the summary statement. This may happen because a summary statement is not meant to be an exhaustive critique; some problems discussed by the reviewers may not appear in it. Also, when you make changes, you risk introducing new problems. Finally, membership in scientific review groups changes. Your application may be seen by some new reviewers who may have different views of your project.

If you do not get funded after the first try, but your application was scored and rejected for Common Fixable Problems try again! Data shows that persistence pays off. NIH allows you ONE opportunity to revise and resubmit the application

Grant Writing

For NIH Researchers

Writing an NIH Grant Proposal

The Basic Components of an NIH Proposal

There are ten basic components that create a solid proposal package:

- **Cover Letter**
- **Project Summary or Abstract**
- **Narrative**
- **Bibliography or References Cited**
- **Environment**
- **Equipment**
- **Biographical Sketches**
- **Budget**
- **Research Plan**
- **Appendices**

Cover Letter

Cover letters are not required, except for late applications or when submitting a corrected or changed version of your application after the deadline has passed. However, the Office of Science Policy strongly recommends including one with every proposal you submit to NIH. They will not be shared with peer reviewers. Investing time and effort to create a cover letter will increase the level of respect, impression of your presentation, and could have an effect on assignment and internal review of your proposal. You should include any of the following information that is relevant to the application:

- **Application title**
- **Funding opportunity** (PA or RFA) and title of the NIH initiative
- **Requests** for assignment or referral to a particular institute, center for funding consideration, or Scientific Review Group (SRG). The NIH is not obligated to grant these requests, but will consider them.
- **Individuals**, competitors, or institutes/centers (IC) who should not review the application should be listed, including your reasoning.
- **Disciplines** involved in the proposed research, if multidisciplinary.
- **Explanation** of any sub-award budget components that are not active for all periods of the proposed grant.

The cover letter should be addressed to the Division of Receipt and Referral (DRR) at the Center for Scientific Review (CSR). Include one of the following salutations: Dear Sir/Madam, Dear Referral Officer, or To

Whom It May Concern. Remember to attach the agency approval documentation to the cover letter file. Additionally, be sure to fill out the title field with the exact name and number of the funding opportunity announcement (FOA). In the required cover letter for a changed or corrected application, you should include:

- **Information** in the previous cover letter, if one was used.
- **Required** explanation of reasons for resubmission.

Any positive or negative requests of particular reviewers should be organized into a list, with one request per line to facilitate consideration. If both IC and SRG review requests are made, place them on separate lines. If you are making positive (a request for referral to a specific SRG) and negative (a request that the proposal not be considered by a particular IC) requests, write them on separate lines as well. Include the name of the IC or SRG followed by a dash and the acronym, but do not use parentheses. Provide explanations for each request in a separate paragraph. See the Cover Letter exercise for an example.

Project Summary or Abstract

This section is intended as a summary of the proposed activity suitable for public presentation or dissemination. It should contain a statement of objectives and methods to be employed. The writing style should accommodate other persons working in the same or related fields and – as much as possible – a lay reader with an understanding of the scientific method. Do not include any proprietary or confidential information in your Project Summary, because it will be available to the general public.

This section is meant to serve as a succinct and accurate description of the proposed work, when separated from the application. For the best results, you should include information about how your project will forward the mission of NIH, as well as how public health will be affected. Both this section and the Narrative should be among the last pieces you write, as they are both summative works. **Keep in mind that your Project Summary cannot exceed 30 lines of text.**

Narrative

The Narrative is the sister section to your Project Summary. You should write this section in plain language that is understandable to a lay audience. Do not include any proprietary or confidential information in the

Narrative, as it will be available for public viewing. Despite the brief nature of your Narrative, do not underestimate the time and effort it may take to get it right. Both this section and the Project Summary should be among the last pieces you write, as they both distill your work down to a handful of sentences. **Most importantly, this section should address the relevance of the proposed research to public health in no more than two or three sentences.**

Bibliography or References Cited

Provide a complete bibliography of any and all references and works cited in your proposal. Each reference must include the names of all authors in the same order of appearance in the publication, the article and journal title, book title, volume number, starting and ending page numbers, and the year of publication. Be sure that you include only bibliographic citations, and consult a style guide to preclude any errors in format.

Include any of your own NIH-funded work within the last three years that has been accepted for publication in a peer-reviewed journal. For these references, you must include the PubMed Central reference number (PMCID) at the end of the citation. See **http://publicaccess.nih.gov/** for more details about compliance with policy.

Environment

Formerly known as Facilities and Other Resources, this section is used to assess the adequacy of the organizational resources available to perform your proposed research. Identify the facilities you will use, such as: laboratory, animal, computer, office, clinical, and/or other. If appropriate, indicate their capacities, pertinent capabilities, and relative proximity and extent of availability to the project. Describe only the resources that are pertinent to your proposed research. You should also provide any information describing other resources available to your project – like machine or electronics shops – and the extent to which they would be available to your project.

The Environment section should address how the available resources will contribute to the probability of success of your proposed research. Be sure to note any unique features or facilities that would lead to the probable success of your research. Early Stage Investigators should also describe

the role of the institutional investment (start-up funding, course release, graduate assistants, etc.) in their own success.

Equipment

You will list major items of equipment available for the project in this section. Include their location and pertinent capabilities, if appropriate. Though this portion of your proposal is simple enough, do not wait until the last minute to think about the details. Remember that this section has an effect on the budget. It also has an impact on the appendix of your project due to detailed equipment descriptions. In turn, the research strategy may affect which items you list here. Do not overstate your capacity in the Equipment section. You can include any lacking resources in the Budget.

Biographical Sketches

Use the sample format provided by NIH. Biographical sketches must be included for all senior or key personnel and other significant contributors. The sketches may not ordinarily exceed four pages per person, including the table at the top of the first page in the sample. Complete the educational block at the top of the page, and the following sections:

- **Personal Statement** – Briefly describe why your experience and qualifications make you particularly well-suited for your role.
- **Positions and Honors** – List in chronological order your previous positions and honors, ending with your current position. You should include present membership on public advisory committees to the federal government.
- **Contributions to Science** – Do not include manuscripts submitted or those in preparation; however, those in press are acceptable. For public citations, URLs, PMCIDs, or submission identification numbers may accompany the full reference. The PMCID is required for any publications subject to the public access requirement discussed in the References Cited section above. The NIH requires that you only cite 15 of your publications: your five most recent, your five best, and the five most relevant to the proposed research. List your publications in chronological order.
- **Research Support** – List selected research projects that are ongoing or have been completed during the last three years, regardless of the funding source. Begin with the projects that are most relevant to your proposed research. You should briefly indicate the overall goals of the projects, as well as the responsibilities of the key person identified

on the biographical sketch. Do not include number of person-months or direct costs. This section is not the Current and Pending Support section. Current and Pending Support information is not required at proposal stage. However, such details will be requested if NIH anticipates making an award to your project. The Research Support portion of the biographical sketch section highlights your accomplishments as a scientist, along with those of your colleagues.

Budget

Personnel or Consortium Justification – When writing your personnel justification, generate a list of personnel. Be sure to include names, number of person-months devoted to the project (academic, calendar, and/or summer), and roles in the project. Do not provide individual salary information. If you are providing consortium justification, you will need an estimate of total costs (direct plus F&A or overhead) for each year, rounded to the nearest $1,000. List the consortium or contractual arrangements that have been made. Include the names of the individuals or organizations, along with all personnel, the percent of effort (in person-months), and roles in the project. Indicate whether the collaborating institution is foreign or domestic, and do not provide individual salary information.

Research Plan

- **Introduction** – (Resubmissions & Revisions Only) Introductions are only allowed for resubmissions or revisions of previously submitted proposals. You will use the Introduction to describe the changes made, and to respond to comments and criticisms presented by the peer reviewers of the previous proposal. If you disagree with any of the comments, explain why. Your Introduction is restricted to one page. Begin each text section of the Research Plan with a section header such as: Introduction, Specific Aims, Research Strategy, etc. Do not use the numbers associated with these sections in the instructions, as your application may not include all of the sections.
- **Specific Aims** – List succinctly the broad, long-term objectives and the goal of your proposed research. For example, to test a stated hypothesis, create a novel design, solve a specific problem, or challenge an existing paradigm or clinical practice, you will address a critical barrier to progress in the field or develop new technology. This section is limited to a single page.

- **Research Strategy** – Depending on the type of application you are submitting, you are allowed either 6 or 12 pages for this section. Those who are preparing the following are limited to 6 pages: R03, R13, R21, R36, R41, or R43. Regardless of the length, the components for your research strategy will likely be:
  - **Significance** – Briefly sketch why this proposed research is significant. Identify gaps in current knowledge or practice which the project intends to fill. You should address an important problem or critical barrier to progress in your field, or in multiple fields. Talk about how the aims of the project will improve scientific knowledge, technical capability, and/or clinical practice. Describe how successful completion of your project's aims will change the concepts, technologies, treatments, services, or preventative interventions that drive your field. State concisely the importance and health relevance of the proposed research by relating the specific aims to the broad, long-term objectives. Your significance sections should about a paragraph.
  - **Innovation** – Your proposed research should challenge and seek to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches, methodologies, instrumentation, or interventions. The concepts should be novel in your field of research, or in a broader sense. Your work should include refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
  - **Approach** – This is the old "Research Design and Methods" section. Describe the research design briefly and the conceptual or clinical framework, procedures, and analyses to be used to accomplish the project's specific aims. Unless specified elsewhere, indicate how the data will be collected, analyzed, and interpreted, and any data-sharing plans, as appropriate. Describe any new methodology and its advantage (s) over existing techniques and practices. You should also describe any novel concepts, approaches, tools, or technologies proposed. Do not forget to discuss the potential difficulties and limitations of the proposed procedures, and alternative approaches to circumvent such limitations where feasible. Provide a tentative sequence or timetable for the

project. If any procedures, situations, or materials may be hazardous to personnel, point them out and describe the precautions that will be exercised.

- **Preliminary Studies** – Your Research Strategy will have either a Preliminary Studies section or a Progress Report. This is the final section of your Research Strategy.
  - **Preliminary Studies** – New submissions will contain this section. If this is a new proposal, provide an account of any preliminary studies done by the PD/PI that are relevant.
  - **Progress Report** – Only renewals and revisions will contain this section. You will provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Discuss any changes in the specific aims as a result of budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials will be included in a separate section; do not include this information in the Research Strategy.

Appendices

Virtually any other supporting information and documents can be placed in the appendix of your proposal. However, beware that you do not include vital project details. The point of your appendices is to relay supplementary information, not to make the case for your project.

- **Multiple PD/PI Leadership Plan** – For projects designating multiple PDs/PIs, a leadership plan must be included. Your rationale for choosing this approach should be described. The governance and organization of the leadership team and the research project should be detailed, including communication plans, the process for making decisions on scientific direction, and procedures for resolving conflicts. Be sure to delineate the roles and administrative, technical, and scientific responsibilities for your project. If budget allocation is planned, the distribution of resources to certain portions of the project or the individual PDs/PIs should be specified here. If you win the

grant, the requested allocations may be relayed in a footnote in the Notice of Grant Award.

- **Consortium/Contractual Agreements** – Explain the programmatic, fiscal, and administrative arrangements you will make between the applicant organization and the consortium organization(s). If consortium or contractual activities represent a significant portion of the overall project, explain why you, not the actual performer of the activities, should be the grantee.
- **Letters of Support** – Attach appropriate letters from all individuals confirming their roles in the project. For consultants, letters should include rates or charges for consultations. Letters of support are not needed for co-PIs or for personnel not contributing in a substantive, measurable way to the scientific development or execution of the project (such as research assistants). Do solicit such letters from collaborators at other institutions, evaluators, consultants, etc. Letters should contain specific commitments and be as descriptive as possible. Do not submit letters from colleagues “in support” of your project.

Common Reasons to Not Fund a Grant

Below is a list of the most common reasons cited by reviewers for an application's lack of success:

- Lack of significance to the scientific issue being addressed.
- Lack of original or new ideas.
- Proposal of an unrealistically large amount of work (i.e., an over ambitious research plan).
- Scientific rationale not valid, or not provided (why important or how relevant to the hypothesis).
- Project too superficial or lacks focus.
- Proposed project is a fishing expedition lacking solid scientific basis (i.e., no basic scientific question being addressed).
- Studies based on a shaky hypothesis or on shaky data, or alternative hypotheses not considered.
- Proposed experiments simply descriptive and do not test a specific hypothesis.
- The proposal is technology driven rather than hypothesis driven (i.e., a method in search of a problem).
- Direction or sense of priority not clearly defined, i.e., the experiments do not follow one another and lack a clear start or end point.
- Lack of alternative methodological approaches in case the primary approach does not work out.
- Insufficient methodological detail to convince reviewers the investigator knows what he or she is doing (no recognition of potential problems and pitfalls).
- Most experiments depend on success of an initial proposed experiment (so all remaining experiments may be worthless if the first is not successful).
- The proposed model system is not appropriate to address the proposed questions (i.e., proposing to study T-cell gene expression in a B-cell line).
- The proposed experiments do not include all relevant controls.
- Proposal innovative but lacking enough preliminary data.
- Preliminary data does not support the feasibility of the project or the hypothesis.
- Investigator does not have experience (i.e., publications or appropriate preliminary data) with the proposed techniques or has not recruited a collaborator who does.
- The proposal lacks critical literature references causing reviewers to think that the applicant either does not know the literature or has purposely neglected critical published material.
- Not clear which data were obtained by the investigator and what others have reported.

In summary, to write a successful research proposal, remember to:

1. Write in plain language with concision

Use simple language, not jargon or advanced technical or medical terms.

2. State your objectives plainly and simply

Describe what you are going to do in detail to achieve your goals.

3. Present a clear plan for carrying out research, including spelling out your methodology and resources

If you cannot answer how you will implement your plan after reading through this section, you will need to do a rewrite.

4. Pick a good topic and address your innovation directly

Be sure that you have answered the following questions: What is new or different about my project? What will I contribute to the existing knowledge or add to the literature?

5. State the following in your plan of operation:

- This is what I will do.
- This is how I will do it.
- This is what I have done.
- This is what is being done now.

6. NEVER complain about lack of resources, and keep your descriptions of available resources short

Discuss: Laboratory space and needed equipment; clinical professionals, environment, and support; animal space, feeding, and health care; computer numbers and capabilities; office equipment can persuade readiness sometimes; and list anything else that might help.

7. Set realistic and reasonable timelines

8. Let colleagues review your proposal before you submit it

9. Remember that the review process is NOT blind

10. Resubmit if you are not funded the first time, but be sure to apply the advice given in the reviews when revising

Persistence pays off. Few people get funded the first time.

11. Speak directly to the issue of fit in your proposal

12. Add a senior collaborator as co-PI or consultant

13. Talk to your program officer in advance

14. Work on something you are excited about!

Questions to Clarify

Your NIH Proposal

Questions to Generate Research Ideas

What is the purpose of your research?

How will you achieve the purpose of your research proposal?

What will change once your proposal is implemented?

How will you know that changes have taken place secondary to the implementation of your proposal?

Why is your idea unique?

Why is your idea timely?

Why is your idea urgent?

Why is your idea compelling?

How will this project capitalize on your department's strengths?

How will this project help your department overcome some of its weaknesses?

Cover Letter Exercise

1. Look at the template on the following page. Note that the review requests are the first portion of the cover letter. The positive requests are made first, followed by the negative requests. The last section contains any miscellaneous information you wish the DRR to know. Remember that this letter is not the place to make a case for your proposal. Instead, the letter is meant to convey urgent information that the DRR needs to know prior to reviewing your proposal.

2. After reviewing the template carefully, use the blank page to write your own cover letter. Try to include as much detail as possible with regard to your requests. Moreover, keep in mind that you are – for all intents and purposes – restricted to one page for your cover letter. Luckily, formatting requirements allow a ½ inch margin for NIH proposals. Make the most of your real estate by employing concision and including only what information is absolutely necessary.

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040 - MSC-7710
Bethesda, Maryland 20817
Proposal 00000

Principal Investigator
Application Title
Funding Opportunity Number and Title

Date

Dear Referral Officer,

Please assign this application to the following:

- Institute/Center
  List here, one per line, and provide rationale for choices
- Scientific Review Groups
  List here, one per line, and provide rationale for choices

Please do not assign this application to the following:

- Institute/Center
  List here, one per line, and provide rationale for choices
- Scientific Review Groups
  List here, one per line, and provide rationale for choices

Include additional information here, if it applies to your situation. For instance:

- explanation of the delay for a late application
- reasoning for submitting a change or corrected application
- rationale for sub-award budget components
- stating that required agency approval documentation is attached

Sincerely,

Your Name
Principal Investigator, Title

Your Cover Letter

Advanced Questions to Narrow Your Focus

Why is your proposal needed to advance the studies within the health care field?

How is your preliminary data relevant?

Why did you choose this way of approaching the gap in knowledge versus other options?

What results will be evaluated in your project?

How will you evaluate the results?

What difficulties might appear within your research plan?

How is your research limited?

General Research Topics

Begin your research proposal by articulating your thoughts concerning a few general topics of interest. Consider the following questions while filling in your responses below: What do you want to do, and how do you see yourself carrying out your ideas? Are your objectives and expectations in line with those of your organization?

1.

2.

3.

Research Problem

Answer the questions below with a few statements or a list. Be as thorough as possible. However, if a particular question requires extensive research, you can simply leave yourself a note in the space provided.

State the bearing on policy and scientific relevance of the problem you will be investigating.

Provide a brief overview of the literature related to this problem.

Describe how your research project will contribute to the solution of the problems identified.

Select a Researchable Question

As you complete the exercises leading to the development of your hypothesis, you will find it useful to rewrite your research question several times. Each revision should reflect greater precision and a narrower scope in your search for an answer.

Begin by posing a question of great interest to you in a simple and nontechnical sentence.

List the resources your research project will require.

1.

2.

3.

4.

5.

6.

Is the research feasible? Yes _____ No _____

Define the important terms in your research question.

	Terms		Definitions
1.		=	
2.		=	
3.		=	
4.		=	
5.		=	

Search for Related Work

List questions you hope are already answered by previous research, followed by the likely source of information (not necessary in journals).

1.

2.

3.

4.

5.

6.

List relevant theories or models, followed by the likely sources of information.

1.

2.

3.

4.

5.

List any other background information you could use, followed by the likely source of information.

1.

2.

3.

4.

Identify the Limitations of Your Study

After struggling to create a design which is feasible and provides control of the most troublesome sources of bias, you may be left with inadequate controls over other sources of bias. Use the space below to identify these.

List any potential sources of bias remaining.

Even unbiased studies have limitations in their capacity to make generalizations. To which people or subjects outside your sample can you now justify generalizing your conclusions? It may be easier to identify individuals for whom your conclusions do not necessarily apply.

Describe the limitations for your potential generalizations.

Data Collection Forms

Use the space below to sketch forms you will use to record the data of the study. Alternatively, you may list and describe the forms below, and then attach specimens at a later date.

Justifying Your Study

Who cares about the answer?

How is present opinion divided?

How important is it to have the right answer?

What are the implications of various possible answers?

Write a paragraph justifying your study. Consider the questions above, but feel free to modify or add to them.

Research Hypotheses

Hypotheses require investigators to predict an answer to a research question based on knowledge of the field, logical analysis, and/or anecdotal observations. Commit yourself to a set of expectations regarding the potential results, even if your study does not require a hypothesis.

Write your research question.

State your initial hypotheses, based on the information above.

List the general relationships implied by your hypotheses.

1._____is related to_____

2._____is related to_____

3._____is related to_____

Identify specific alternative relationships or explanations, which would serve as competing or rival hypotheses, if possible.

1.

2.

3.

Write your revised hypotheses, considering specific competing alternatives to the hypothesized relationships (if applicable).

Research Methods

List the variables or factors to be measured during your research project.

Describe the population and samples to be used in your data gathering, including explanations of sampling or selection procedures, if relevant.

In consideration of your working hypotheses, describe the methods you will apply to collect primary and secondary information.

Indicate any relevant biases in your methods, and the means by which these biases would be overcome in this project.

Provide your analysis of information.

Generating SMART Specific Aims

The Specific Aims of winning projects are specific, measurable, attainable, realistic, and time-bound. Use the first half of this worksheet to generate working Specific Aims for your project. Then, verify they meet the standards set above in the second half of this worksheet. If necessary, revise your Specific Aims in the space provided under each question. **Remember:** No more than 2 or 3 Specific Aims per proposal!

What are the overall aims of your research project?

List the unresolved issues directly addressable by your methodology.

Do your Specific Aims match what you want to accomplish? If not, revise.

Do your Specific Aims include testable concepts and ideas? If not, revise.

Do your Specific Aims define why your research matters? If not, revise.

Do your Specific Aims incorporate your timeline? If not, revise.

Do your Specific Aims avoid describing your methods? If not, revise

Expected Results and Dissemination

To plan your project strategically, consider the potential outcomes of your project. Think about the impact your results might have on other studies in your field, or in other fields of research. Answer the questions below with as much detail as possible.

Describe the expected outcomes of your project.

What form or format will your results take?

How do you plan to record, capture, or otherwise document your results?

Outline your plan to disseminate your results.

Personnel

The best research proposals make a strong statement about the project personnel and their qualifications to conduct the research. You may not have a team, but you will almost certainly have a mentor. Elaborate on your and/or your mentor's prior experience and training in your answers below.

Describe you and/or your mentor's education in chronological order.

Describe you and/or your mentor's positions held and other experience, and how each applies to your project.

List up to 15 published research articles relevant to your project, and that are authored by you and/or your mentor.

List all the ongoing and completed research within the last three years that applies to your project, regardless of the funding source.

Describe the role and responsibilities for each significant contributor of your project.

Timetable

If your intended granting agency has already designated a specific timetable, use their plan. Otherwise, outline your anticipated project dates, deadlines, and milestones in the space below

Budget

Prior to forming a budget, consult with your sponsored research office. It is imperative that institutional protocols are followed at this stage. For many research projects, the budget is not scored. However, a poor budget plan may negatively impact your proposal's chances of getting funded.

Direct Research Costs: Salaries, supplies needed, expenses, equipment (if allowable by sponsor), and travel. Do not forget simple items, such as brochures, educational materials, specific postage required, etc.

Overhead: What is the correct applicable indirect cost for this project? Consult with your institution to calculate overhead charges.

Instruments and Data Sources

Complete this inventory of measurements or counts to be made.

Measured or Counted Items	Necessary Instrument or Data Source	Available?
1._____	_____	Yes / No
2._____	_____	Yes / No
3._____	_____	Yes / No
4._____	_____	Yes / No
5._____	_____	Yes / No
6._____	_____	Yes / No
7._____	_____	Yes / No
8._____	_____	Yes / No

Indicate critical characteristics of instruments to be found or developed for items above marked "No."

Proposed Instruments	Critical Characteristics
1._____	_____
2._____	_____
3._____	_____
4._____	_____

A note regarding instrument reliability and validity:
Reliability: How closely do repeated observations (by different people at different times, etc.) of the same thing agree with each other?
Validity: What assurance do you have that the instrument is measuring what you believe it is measuring?

Mark the number of the above instruments with an **R** if you believe reliability is a problem, and a **V** if you believe validity is a problem.

Preparing Your Research Design

The design of a study refers to the way in which relationships are to be studied. Seek competent help in preparing a research design, since the options are numerous. Choosing a design will always require a compromise between the practical and the ideal. Well-designed research should be more efficient and better suited to your needs than a haphazard approach. Poorly-designed research may be inefficient, or – even worse – may make it impossible for you to analyze the data legitimately! Carefully consider design when answering the questions in the sections leading up to eliminating your procedural bias.

List the people whose design expertise may be helpful to you, as well as an anticipated contact date.

Sample Size

The most important considerations when determining sample size are how much money you have to spend, and how much time you can commit. Increases in sample size lead to more precise results. Once other design features have been worked out, your research consultant should be able to help you arrive at a reasonable sample size. A large sample should enable you to detect more subtle, but perhaps less important, relationships. The most helpful information for your decision comes from the results of similar studies, and your estimate of the strength of the relationships you expect to find.

Provide a working estimate of your sample size below, as well as your reasoning for the number.

Sampling

Describe the characteristics of the people (or other subjects) who will be eligible for participation in the study.

Describe the population (beyond your sample) about which you wish to draw general conclusions.

Review the two descriptions critically. Do they make sense when paired together? If not, revise the descriptions to create a better match. Write your modified descriptions below.

Study subjects:

Population:

Developing Your Research Protocol

This worksheet will help you flesh out your research design. The more detail you can provide, the better your preliminary proposal will be.

Describe how you will select your sample.

Discuss whether you will divide your sample into groups, and how so.

Explain what will happen to each subject using a narrative, list, flow chart, or diagram.

Describe how data will be gathered, and by whom.

Eliminating Procedural Bias

Procedural bias refers to sources of systematic error which may affect study results. Your design should evolve as you add controls for the most serious sources of bias. With your general protocol in mind, special attention should be given to these potential obstacles to clear results.

Effects of Historical Events

Can you anticipate events – such as personnel changes, remodeling plans, or interference by nonparticipants – which will take place during your data collection phase, and which might affect the results?
No_____ Yes_____ (If yes, describe problem.)

Effects of Maturation

If subjects are to be observed over a certain amount of time, are there changes which might result merely by normal development, growth, natural course of illness, etc.?
No_____ Yes_____ (If yes, describe problem.)

Effects of Repeated Measurement

If the same measurements are repeated on subjects, are subjects likely to remember past responses, prepare differently for the next session, or are the observers likely to relax procedures?
No_____ Yes_____ (If yes, describe problem.)

Instrument Decay

Is it likely that test equipment will wear out, observers get bored, or are investigators likely to shortcut protocols, etc.?
No_____ Yes_____ (If yes, describe problem.)

Effects of Statistical Regression

If subjects are chosen because they lie at the extremes of a distribution (eg, high blood pressure, low compliance with therapy), subsequent measurements will tend to be more nearly average, for purely statistical reasons. Are your subjects chosen or assigned to groups on the basis of their extremity?

No_____ Yes_____ (If yes, describe problem.)

Subjects Selection

Is there any factor in the selection of your sample – or assignment of subjects to groups – which makes one group of subjects unintentionally different from other groups?

No_____ Yes_____ (If yes, describe problem.)

Loss of Subjects

Subjects lost to attrition may be different from those who remain. Is your study jeopardized by this possibility?

No_____ Yes_____ (If yes, describe problem.)

Investigator Bias

Are you in a position to unintentionally "shade" results to confirm your hypotheses or to influence subjects by your attention, attitude, etc.?

No_____ Yes_____ (If yes, describe problem.)

The above examples are adapted from "Experimental and Quasi-Experimental Design for Research," Campbell DT and Stanley JC, Chicago, Rand McNally College Publishing, 1966.

Reporting of Results

Use the space below to sketch summary data tables and/or graphs which you would expect to use in presenting your results. You may include simulated results of the kind you hope to find.

Statistical Analysis

Design and analysis are two sides of the same inferential coin. Always seek competent consultation from statisticians during the design phase, or there may never be any analysis worth doing.
List the people whose expertise in statistical analysis may be useful.

Begin to organize your analysis by listing all of the variables considered in your design, divided into the three categories described below:

List the demographic variables which describe characteristics of subjects such as age, sex, race, previous hospitalizations, etc.

List the variables of the study under the control of the investigator, such as type of instruction given, therapy options, duration of treatment, or other exposures or treatments to which the investigator can assign subjects.

List the outcome variables or effects potentially related to or caused by A or B above, such as adherence to instructions, speed of recovery, or client satisfaction.

Discussions, Interpretations, or Conclusions

No workbook exercises are included for this phase of your study. Instead we suggest that you maintain a notebook or fieldwork journal to capture anecdotes, remarks of subjects, comments by others involved in the project, or any other facts or ideas which might help to make sense out of the phenomena under study. The serendipity of an alert and curious researcher leads to insightful interpretations and fruitful new hypotheses.

Administrative Arrangements

The most elegantly designed studies can collapse for lack of attention to administrative details.

Outline your administrative duties in the space below.

	Contact	Regarding
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____

Describe other administrative arrangements in the space below such as: money, equipment, supplies, space, printing, consultation, postage, telephone, or computer programming.

Dr. Michael Gordon, Research Assistant & Professor Department of Family Medicine, University of Washington, Seattle, WA

Grant Section

Examples

For NIH Researchers

Finding Examples

This chapter includes examples of abstracts, specific aims, statements of significance, a biographical sketch, and a data sharing plan. However, we do not have the space to include examples from every genre of research. To find the best examples of successful NIH proposals in your field, start with faculty at your institution with whom you are acquainted. If they have been funded by NIH, they could be a valuable resource for advice and writing tips.

The other source of examples – which may be more reliable than your colleagues – is the NIAID website. The agency provides many examples from various genres of biomedical research. Click on the link below to visit the Samples and Examples page:

http://www.niaid.nih.gov/researchfunding/grant/pages/samples.aspx

Many different genres of research are represented by the examples included on the page. Additionally, you can find full applications for R01, R21, and R33 grants by looking under the "Highlights" section to the far right, and clicking on "Sample Applications."

Judging Criteria

NIH Judging Criteria

- **Significance:** Importance of the problem, potential impact on the field
- **Approach:** Experimental design, pitfalls, and alternatives
- **Innovation:** Originality and novelty of the concepts, challenge to dogma
- **Investigator:** Training, experience, integration of the team
- **Environment:** Institutional resources, uniqueness of subject populations

NIH Scoring Grid

Score	Descriptor	Additional Guidance on Strengths & Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

- **Non-numeric score options:** NR = Not Recommended for Further Consideration; DF = Deferred; AB = Abstention; CF = Conflict; NP = Not Present; ND = Not Discussed
- **Minor Weakness:** An easily addressable weakness that does not substantially lessen impact
- **Moderate Weakness:** A weakness that lessens impact
- **Major Weakness:** A weakness that severely limits impact

NIH Abstract Example #1

Project Title: UNRAVELING CRUCIAL ROLES OF HOMEOBOX GENE HLX IN HEMATOPOIESIS AND LEUKEMOGENESIS

DESCRIPTION (provided by applicant): While isolation of stem cells has advanced dramatically in the last few decades, understanding of the precise mechanisms that regulate the self-renewal and lineage commitment of a stem cell is still limited. During hematopoiesis, progeny of hematopoietic stem cells (HSC) become committed to differentiate into specific cell lineages to ultimately generate terminally differentiated cells. Transcription factors have been recognized for their ability to drive expression of a characteristic set of lineage-specific target genes, instructing a precursor cell to adopt a certain differentiation program. Dysregulation of transcription factor activity has an important role in leukemia, implicating these genes as potential targets for therapeutic intervention in blood, and other forms of cancer. When we analyzed purified pre-leukemic hematopoietic stem and progenitor cells (HSPC) in a murine acute myeloid leukemia (AML) model, we found 4-fold upregulation of a novel non-clustered homeobox gene, H2.0-like homeobox (Hlx), suggesting that Hlx may be involved in healthy hematopoiesis and malignant transformation. Our preliminary studies indicate that overexpression of Hlx disrupts healthy myeloid differentiation and confers unlimited serial clonogenicity and a myelomonocytic differentiation block to hematopoietic stem and progenitor cells in vitro. Furthermore, overexpression of Hlx causes loss of phenotypic HSC and persistence of an expanded, aberrant myeloid progenitor population in vivo. We also find that Hlx regulates a network of genes important for lineage commitment and myeloid differentiation of HSPC. Strikingly, we find that Hlx is overexpressed in the majority of patients with AML, and that Hlx expression is one of the strongest predictors of AML patient survival. We also find that Hlx downregulation inhibits growth of murine and human AML cells in vitro. This project aims to understand how Hlx is regulating these critical functions in HSC and during myeloid differentiation. To characterize the roles of Hlx in lineage commitment of stem and progenitor cells, as well as in myeloid differentiation and acute myeloid leukemia cells, we will utilize genetic murine models, stem cell transplantation assays and targeted reduction of Hlx levels in vivo and in vitro. To elucidate the mechanism of action of Hlx, we will study downstream pathways we have identified by transcriptional profiling and perform chromatin-immunoprecipitation to establish Hlx as a transcription factor capable of directly regulating its target genes. PUBLIC HEALTH RELEVANCE: The goal of this project is to understand the functions of the non-clustered homeobox protein Hlx in healthy hematopoiesis and in leukemia pathogenesis. To characterize the roles of Hlx in lineage commitment of stem and progenitor cells, as well as in myeloid differentiation and acute myeloid leukemia cells, we will utilize genetic murine models, stem cell transplantation assays and targeted reduction of Hlx levels in vivo and in vitro. To elucidate the mechanism of action of Hlx, we will study downstream pathways we have identified by transcriptional profiling and perform chromatin-immunoprecipitation to establish Hlx as a transcription factor capable of directly regulating its target genes.

NIH Abstract Example #2

Project Title: IMPLICATIONS OF JAIL INMATES' PERCEIVED STIGMA FOR POST-RELEASE SUBSTANCE DEPENDENCE

DESCRIPTION (provided by applicant): Stigma is implicated as a major barrier to the successful reintegration of criminal offenders into the community. However, research has yet to examine stigma from offenders' perspectives, and the mechanisms by which stigma leads to negative consequences for offenders are unknown. Research with other stigmatized populations shows that individuals' perceived stigma toward their group is linked to consequences such as poor mental health, unemployment, and poor community functioning through psychological processes (i.e. internalized stigma) and coping strategies (e.g. withdrawal, alienation). Further, research is beginning to show a link between perceived stigma and risk behaviors such as substance abuse and increased risk for HIV. Research and theory suggest that people vary in how they respond to stigma, creating variability in psychological and behavioral consequences of stigma. This project aims to test a comprehensive model of offenders' subjective experiences with stigma to determine how perceived stigma predicts post-release behavior including substance dependence, recidivism, mental health, employment, and community functioning. The proposed models are drawn directly from conceptual theories of stigma found in psychological research. This project will draw upon two existing longitudinal studies with jail inmates; one dataset has already been collected (N = 168) and the other is currently being collected (N 100). Inmates' perceived stigma prior to their release will be analyzed in relation to post-release variables. Several theoretically-driven mediators and moderators of this relationship will be analyzed. Specifically, this project will test the hypothess that perceived stigma predicts post-release outcomes through anticipated stigma; post-release outcomes are hypothesized to be negative when inmates think and cope in maladaptive ways after their release (e.g. social withdrawal), and positive when inmates think and cope in adaptive ways (e.g. stigma resistance). Additionally, this project will test the hypothesis that inmates come to anticipate stigma when they internalize their perceptions of stigma. This project will test whether this process varies as a function of inmates' race, optimism, shame-proneness, and social identity as a criminal. Findings from this study will identify multiple emotional and cognitive avenues of intervention that can be addressed in treatment services for offenders. These findings will not only identify how to prevent negative responses to perceived stigma (e.g. internalized stigma) and negative outcomes (e.g. substance abuse, recidivism, unemployment), but it will identify how to enhance positive responses to stigma (optimism, stigma resistance) and increase positive outcomes (e.g. psychological health, sobriety, prosocial community functioning). Ultimately, these findings will fill a substantial gap in the scientific literature o stigma, and will focus on offenders as an understudied, high-risk, stigmatized population. By identifying malleable variables that can inform correctional treatment and reentry services for offenders, this project's primary goal is to decrease criminal behavior and improve general community well-being. PUBLIC HEALTH RELEVANCE: This project will investigate how offenders' perceived stigma predicts post-release drug use, crime, mental health, employment, and community functioning. By identifying stigma-related treatment targets, this project aims to enhance the community integration of offenders and reduce the burden of crime on society.

NIH Abstract Example #3

Project Title: INTRAVENOUS PROTEIN THERAPY FOR MYOTONIC DYSTROPHY TYPE I

Our objective is to develop intravenously delivered recombinant Muscle Blind 1 (MBNL1) for patients with Myotonic Dystrophy Type 1 (DM1). DM1 is the most common muscular dystrophy of adulthood and is caused by a large CTG expansion in the 3' untranslated region of the DMPK gene (1-3). Although the function of DMPK and the neighboring Six5 gene are negatively affected by the CTG expansion, the lack of DMPK activity does not fully account for the observed phenotype in DM1; including muscle wasting and myotonia, insulin resistance, testicular atrophy, cutaneous tumors cardiac arrhythmia and cognition defects (4- 8). Subsequent studies have shown that the large CUG expansion within the transcribed DMPK mRNA avidly binds, sequesters and inactivates the MBNL1 protein, an mRNA splicing factor that removes fetal exons from mRNA templates (9- 13). The inactivation of MBNL1 by polyCUG expansions or through Genetic ablation of MBNL1 results in the inappropriate expression of fetal Proteins in adult differentiated tissues (9, 14- 17). Though sequestration of MBNL1 clearly cannot provide a unitary explanation for DM1, evidence from transgenic mouse and fly models, and studies of patient-derived cells, supports the idea that symptoms of DM1 are partly determined by the stoichiometry of CUG expansion RNA in relation to ambient supplies of MBNL1 protein (18, 19, 20). The consensus in the DM1 community is that any approach that restores the availability of MBNL1 Proteins for mRNA splicing would constitute a therapy for DM1 (21, 20). Treatment options being considered for DM1 include [1] small-molecule induced overexpression of endogenous MBNL1, [2] disruption of the polyCUG- MBNL1 association through small-molecule and nucleotide-based therapies, [3] transgenic overexpression of MBNL1 via gene therapy, and [4] direct intravenous application of exogenous MBNL1. 3E10 is a murine-derived monoclonal antibody that penetrates living cells and localizes to the cell nucleus without apparent injury to target cells (22, 23). A single chain Fv fragment of 3E10 (Fv3E10) possesses all the cell penetrating capabilities of the original monoclonal antibody and Proteins such as catalase, dystrophin, HSP70 and P53 retain their activity following conjugation to Fv3E10 (24-27). The ENT2 nucleotide scavenger transporter is enriched in skeletal muscle and cancer cells and mediates the cell-penetrating ability of Fv3E10 and Fv3E10 conjugates (28). Given the affinity of Fv3E10 for skeletal muscle and the ability of Fv3E10 conjugates to maintain their respective activities, Fv3E10-based therapies would represent a versatile approach to treat many myopathies, including DM1, DM2, Duchenne muscular dystrophy and Emery-Dreifuss syndrome. We seek funding for two years to translate 3E10 and MBNL1 into a commercially viable product for DM1. We will chemically or genetically conjugate 3E10 to MBNL1, test the purified material in DM1 cell lines, inject the purified material into DM1 mouse models and evaluate any correction of the disease endpoints. To execute this proposal we have gathered the appropriate technology, the commitment from the biotechnology industry, and the expertise and resources of the DM1 scientific and patient advocacy community. Successful conclusion of this proposal will justify further product optimization, including examination of truncated and/or humanized 3E10-MBNL1 and determination of the optimal manufacturing process. The final product concept will undergo further efficacy, pharmacology and toxicology studies, scaled-up GLP production, additional pre- IND pharmacology and toxicology studies, and upon FDA approval the development of phase 1 and 2 clinical trials. PUBLIC HEALTH RELEVANCE: Myotonic dystrophy is the most common muscular dystrophy of adults for which there are no effective therapies. We will test if a muscle-targeted Muscleblind protein therapy will alleviate the spliceopathy in DM1 mouse models.

Statement of Significance Worksheet

Filling out this worksheet will help you tell your story in a compelling, convincing, clear and specific manner. Answer the questions below with as much detail as possible.

What is the problem my research addresses?

Consider timely statistics, focus on your solution, and succinctly state what is necessary to solve the problem.

Keeping in mind that this section is usually followed by the hypothesis and specific aims section, briefly describe what it will take to solve the problem.

Statement of Significance Example #1

Proposal Title: Structure and Function of Flaviviruses

The amount of structural information on flaviviruses has greatly increased during the last five years [**47**], the period of our previous Program Project Grant (1 P01 AI055672). During this time, using a combination of crystallography and cryoEM, we have determined the structure of the immature [**3, 4**] and mature [**12, 27, 28**] dengue and West Nile viruses, the post-fusion structure of the external glycoprotein has been determined [18, 19] and complexes of flaviviruses with receptor [**6**] and neutralizing antibodies [**48**] have been the subject of structural studies. These results show that there are enormous conformational changes that occur during virus maturation, host cell recognition and fusion with the host cell. These dynamic events are at the center of the virus life cycle and would be the target of many antiviral strategies. However, there is currently little or no information on the mechanisms that guide and direct these enormous structural transitions. The various specific aims of this grant application are directed to intercept the virus in its assembly and infection processes. We have started to use antibodies, pH adjustments, and rapid freezing techniques to study the various intermediates, as well as improving the resolution of all present and future structural investigations. These studies are also starting to provide information on the various mechanisms by which antibodies neutralize flaviviruses.

It has been our universal experience that inspection of structure, when newly available, is a wonderful stimulus to answer questions about how the structure functions to perform its multiple tasks. The various structures of flaviviruses and their assembly and functional intermediates that we anticipate will become available during the tenure of this grant is likely to lead to fuller analyses of the viral assembly pathway, the initial virus-cell recognition event, and the endocytotic processes that lead to fusion with the cell membrane. In addition, we anticipate that the knowledge we will gain by the study of flaviviruses will be applicable to many other viral systems.

Statement of Significance Example #2

Proposal Title: Resistance Suppression for Influenza Virus with Combination Chemotherapy

Mathematical modeling of pandemic influenza suggest that such a pandemic could be controlled with the judicious use of antiviral drugs, wide spread vaccination against pandemic influenza strains, and non-pharmaceutical measures such as school closing and working from home, etc (70-75). Thus, with the appropriate use of nonpharmaceutical interventions and antiviral drugs in the short term and vaccination in the long term, it should be possible to contain epidemics and pandemics caused by avian or human influenza viruses. Now the questions that remain are: how much drug to give and how often does one have to give that much drug to prevent infection or cure a patient infected with epidemic or pandemic strains of influenza virus without allowing resistant viruses to emerge during therapy? We **hypothesize** that there is an optimal dose of each of these influenza virus drugs or combinations of drugs and an optimal schedule of administration of these drugs and combinations of drugs that will prevent and/or cure infection with avian or human influenza viruses without leading to the emergence of drug resistant viruses during therapy.

Since it will not be possible to determine the effect of these antiviral compounds on H5N1 or other epidemic and pandemic influenza virus infections in people in the standard phase II – III clinical trials, we shall use our *in vitro* HFIM system, developed by Dr. Drusano, the PI of this grant application (7- 16), to determine the optimal dose and administration schedule for amantadine (for type A viruses) and oseltamivir carboxylate for type A and type B viruses. Several H1N1 and H3N2 human influenza A viruses, the recombinant virus, rgA/Vietnam/1203/2004 X A/PR/8/34, (a surrogate for H5N1 influenza virus), and type B viruses will be tested. Once we have determined the pharmacodynamically-linked variable for each of these antiviral compounds given as monotherapy for these viruses, we will determine the effects of combinations of these compounds on virus replication in the HFIM system. Since it is known that treatment of influenza virus-infected individuals with the amantadine or oseltamivir carboxylate can lead to the emergence of drug resistant viruses during therapy (1-6), a major aim of this proposal will be to determine the dose and schedule of administration of these drugs that will suppress the emergence of resistant viruses when these drugs are delivered as monotherapy or in combination therapy.

Statement of Significance Example #3

Proposal Title: Effects of Attention Disorders on Developing Cognition: Mechanisms and Plasticity

A fundamental question about human cognition is the extent to which it is predetermined to take its adult shape, or is instead malleable and dependent on learning from the environment. This question naturally brings researchers to investigate the early development of cognitive functions, and theoretical positions have coalesced around distinct alternatives. Nativists propose that infants come to the world equipped with a sophisticated armament of skills and conceptual knowledge. Claims of innate specification of cognitive domains have been bolstered by dissociations of function in individuals with developmental disorders, especially those associated with a known genetic aetiology. Constructivist accounts instead see environmental input as instrumental and question the notion of developmental disorders as islets of intact and impaired ability.

A way to turn impasse into dialogue is to ask how domain-specific knowledge emerges through domaingeneral processes such as attentional control: active selection of information in the environment gates processing into short-term and long-term memory. Executive processes also provide the mental workspace necessary to select or ignore, update and maintain information online and therefore constrain domainspecific learning both concurrently and longitudinally. Attention and executive deficits could lead to cascading effects across many domains of cognition, with uneven cognitive profiles resulting from interactions between attentional biases and characteristics of the to-be-learned information. In this context, studying individuals with disorders of attention and executive control from early childhood, rather than just in adulthood, has the potential to assess disorders' role in substantiating the innate specification and modular structure of cognition.

Work in my laboratory has investigated disorder-specific profiles of early attention difficulties in developmental disorders that are either genetically or functionally defined, as well as their trajectories and outcomes on behaviour and cognition. Understanding how distinct attention disorders affect cognitive processes has required a prospective longitudinal approach and experimental paradigms that can tap attention and executive control in young and less able children. In a complementary fashion, we study optimal interactions of attention and executive control with memory and learning over typical development, from early childhood into adulthood.

The data emerging from these studies at the interface between attention disorders and their cascading effects on cognition have generated novel questions. How do deficits influence interactions with naturalistic environments? Are attention deficits predetermined to follow their course, or instead malleable? I propose to study how attention and executive control mediate outcomes across cognitive domains and in everyday situations such as complex classroom environments. Importantly, in order to test the plasticity of attention difficulties and their effects on other cognitive processes, I propose to contrast controlled training regimes that modify domain-general mechanisms like attention (training children in "how to learn") with domainspecific interventions (training them on "what to learn"). These two complementary approaches will target core questions about mechanisms fostering the developing mind, because they will test the efficacy and specificity of attention training effects across cognitive domains, and the extent to which attention deficits associated with an identified genetic aetiology or high familial risk are amenable to environmental influences.

Biographical Sketch Example

BIOGRAPHICAL SKETCH Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**	
NAME Hunt, Morgan Casey	POSITION TITLE Associate Professor of Psychology
eRA COMMONS USER NAME (credential, e.g., agency login) huntmc	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Merryle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. Psychology and Aging, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. Hunt, M.C., Wiechelt, S.A. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292
4. Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

B. Positions and Honors

Positions and Employment

1998-2000 Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001- Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007- Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995- Member, American Psychological Association
1998- Member, Gerontological Society of America
1998- Member, American Geriatrics Society
2000- Associate Editor, Psychology and Aging
2003- Board of Advisors, Senior Services of Eastern Missouri
2003-05 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11 NIH Risk, Adult Addictions Study Section, member

Honors

2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004 Excellence in Teaching, Washington University, St. Louis, MO
2009 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

   a. Gryczynski, J., Shaft, B.M., Merryle, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
   b. Shaft, B.M., Hunt, M.C., Merryle, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.
   c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),26-37.
   d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.

   a. Hunt, M.C., Merryle, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.
   b. Hunt, M.C., Pour, B., Marks, A.E., Merryle, R. & Jensen, J.L. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
   c. Merryle, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364

3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.

   a. Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. Journal of the Geriatrics, 60(4), 45-61.
   b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
   c. Merryle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304
   d. Hunt, M.C., Jensen, J.L. & Merryle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmjWAO/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

R01 DA942367-03 Hunt (PI) 09/01/08-08/31/13
Health trajectories and behavioral interventions among older substance abusers
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

R01 MH922731-05 Merryle (PI) 12/15/07-11/30/12
Physical disability, depression and substance abuse in the elderly
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
Role: Co-Investigator

Faculty Resources Grant, Washington University 08/15/09-08/14/11
Opiate Addiction Database
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Completed Research Support

K02 AG442898 Hunt (PI) 02/01/02-01/31/05
Drug Abuse in the Elderly
Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.
Role: PI

R21 AA998075 Hunt (PI) 01/01/02-12/31/04
Community-based intervention for alcohol abuse
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
Role: PI

Data Sharing Plan Example

Sharing of data generated by this project is an essential part of our proposed activities and will be carried out in several different ways. We would wish to make our results available both to the community of scientists interested in [this disease] and the biology of [its causative agent] to avoid unintentional duplication of research. Conversely, we would welcome collaboration with others who could make use of the vaccine assessment protocols developed in [the project].

Our plan includes the following:

Presentations at national scientific meetings. From the projects, it is expected that approximately four presentations at national meetings would be appropriate. There is an annual [Disease] Study Group meeting, of which the PI is secretary. This one-day meeting of interested persons presents new information on a variety of topics related to [the disease]. It is expected that the investigators from this [project] will be active participants of this focused group.

Annual lectureship. A lectureship has brought to the University distinguished scientists and clinicians whose areas of expertise were relevant to those interested in [the disease]. Lecturers have been [list of names]. Visiting lecturers will be scheduled to interact with the investigators of the project as appropriate with their specific areas of expertise which will provide an opportunity for members to present their work to the visitor.

Newsletter. The [disease interest group] publishes a newsletter which currently has a circulation of [number]. The newsletter's intent is to disseminate new information regarding [the disease]. The activities and discoveries of [the project] will be allocated 20% of the newsletter's coverage.

Web site of the Interest Group. The [interest group] currently maintains a Web site where information [about the disease] is posted. Summaries of the scientific presentation from the [quarterly project] meetings will be posted on this Web site, written primarily for a general audience. [Link to Web site]

Annual [Disease] Awareness week. Beginning this fall during the week of [date], the [interest group] will be sponsoring a [Disease] Awareness week. As part of that program, there will be a research poster display with discussions. In future years, [the project investigators] will be active participants in this program.

SAGE Library Data. [This project] will generate data from several SAGE libraries. It is our explicit intention that these data will be placed in a readily accessible public database. All efforts will be made to rapidly release data through publication of results as quickly as it is possible to analyze the experiments.Data used in publications will be released in a timely manner. SAGE data will be made accessible through a public site that allows querying as has been set up for a similar project. This site can be accessed at [link to Web site].

Useful Tools & Templates

Defining Your Hypothesis & Specific Aims

For your proposal to come together, begin using the information from the worksheets you completed earlier in the workshop. To help you tighten down your research project, review the definitions below. Think about how these terms are represented in the examples that follow.

Hypothesis: The purpose of your project or program.

Specific Aims: These are the methods you will use to accomplish your goal. They should be specific, measurable, achievable, realistic, and time-bound.

Grant Design

On the following page, you will find a blank hypothesis and specific aims chart. Each specific aim has three activities with space allotted to describe the details. When filling in the chart, consider the way your specific aims refer back to your hypothesis. Also note how each activity directly impacts the success of the parent specific aim.

Grant Design Chart

Hypothesis:						
Specific Aims	Methodology	Begin/End Dates	Personnel	Outcomes		
				Short	Mid	Long
A.	A-1:					
	A-2:					
	A-3:					
B.	B-1:					
	B-2:					
	B-3:					
C:	C-1:					
	C-2:					
	C-3:					

Timelines & Graphics

Your timeline is a realistic assessment of the time needed to meet your goals. Answering the questions below will help you create yours.

How long do you need to achieve your goals and why?

Outline the time it will take you to achieve your goal.

Why did you decide on the above timeline?

What is the timeline for spending the funds?

If you use graphics to describe the timeline, sketch the form the visual aid will take in your proposal.

Gantt Charts

Gantt charts are graphic representations of a project's timeline. They portray the scope of a project, which allows you and your personnel to view the proposal writing and planning process as a whole. Since Gantt charts provide an overall perspective, decision-makers can understand how changes to one section affect the whole. Using this timeline tool is an easy and straightforward way to track tasks, responsibility, and due dates from inception to conclusion.

When using a Gantt chart, be sure that your timeline is realistic. Your chart can help you successfully plan your proposal writing process, but it is only as good as the information that you put into it. For instance, it is best to design your project to fall within the grantor's funding cycle. A Gantt chart can help you determine the appropriate amount of lead time necessary to make such a scenario occur.

Many project management tools may be found online. One free version that facilitates online collaboration via the cloud is found at:

www.gantter.com

The site hosts a free, web-based project management tool with project templates for scheduling, and the capacity to save to either Google Drive or the Gantter cloud. Some other benefits are:

- Gantter requires nothing but a web browser. Simply go to the website and select the “Start Now” button to begin project planning.
- Your Google Drive items can be integrated. You can save and open schedules, share schedules with other users, and collaborate with those users in real time.
- Microsoft Project files can be imported or exported for ease of data transfer.
- The project schedule tool creates Gantter Project Schedules directly from inside of Google Drive after installing an extension.
- The site provides 11 languages for collaboration worldwide.

Sample Gantt Chart

WEEKS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Defining & Understanding the Problem																	
Problem Definition																	
Preliminary Analysis																	
Objectives	::::																
Feasibility Study	////																
System Modeling	- - -																
Planning & Defining of Solutions																	
Storyboard																	
Data Dictionary																	
Algorithms																	
Structured Diagrams				::::													
Syntax Descriptions					////	////											
Structured walkthrough							////										
Screen Diagrams																	
Implementing Solutions																	
Development Diary																	
Developing the Solution																	
Documentation of Stubs & Flags							- - -	- - -									
Online Help									::::	::::							
Testing & Evaluation of Solutions																	
Test Data Dictionary																	
Checklist of Objectives																	
End User Testing & Feedback																////	
Visual User Testing & Feedback																	
Maintenance of Solution																	
Modifying the Solution																	

The Logic Model

SITUATION:

PRIORITIES:

INPUTS	OUTPUTS		OUTCOMES		
	ACTIVITIES	PARTICIPATION	SHORT	MEDIUM	LONG-TERM
ASSUMPTIONS 1. 2. 3.			EXTERNAL FACTORS 1. 2. 3.		

Evaluation

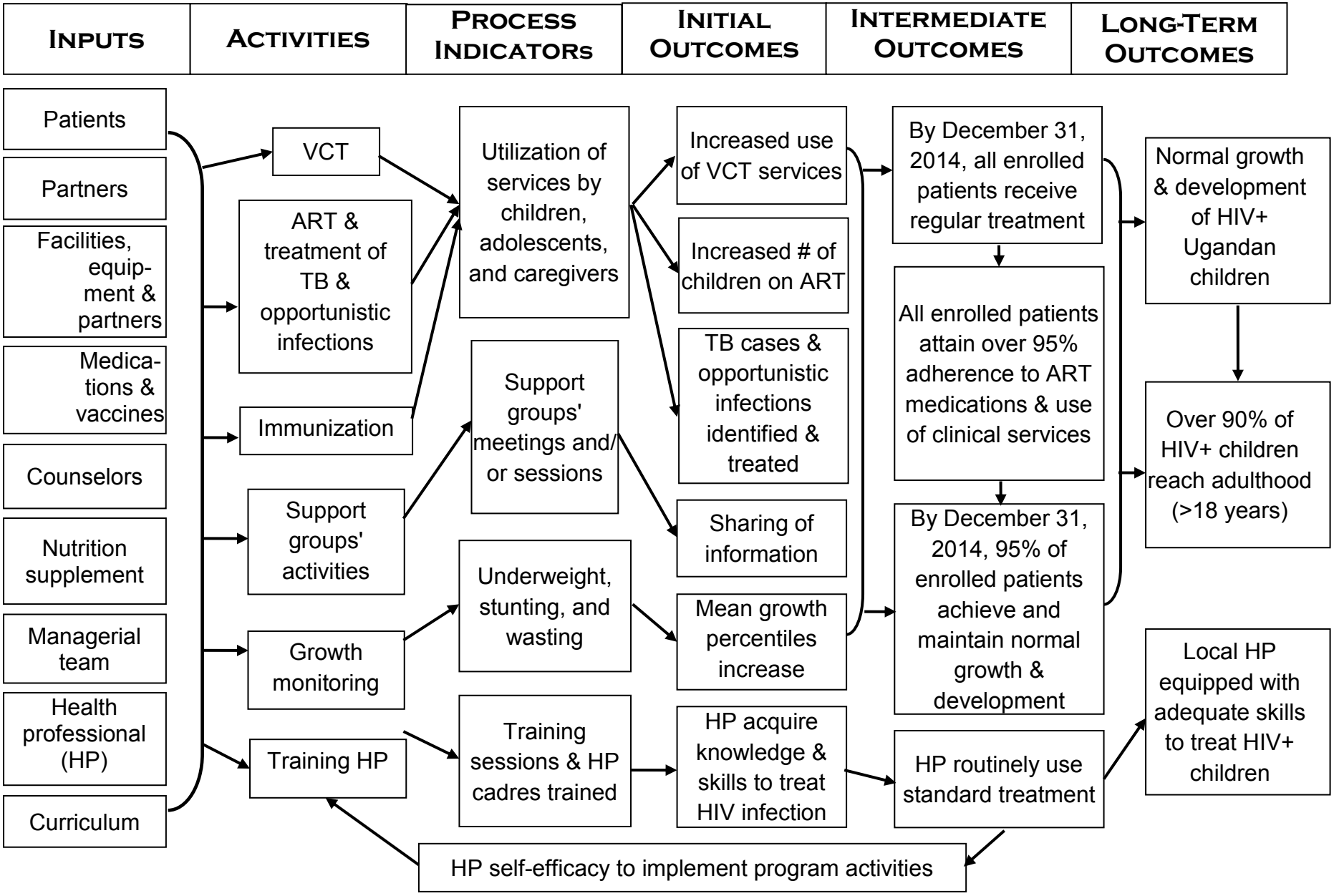
What do you want to know?

How will you know it?

NOTE: The number of boxes and design will vary depending upon your program and situation. Include arrows to show directional flows.

Logic Model Example #1

Pediatric HIV Treatment & Training Program in Uganda



Budgets

Budgets vary according to donor. Be sure that you budget reflects the specifications of the RFP. Please answer the following questions in relationship to your budget.

How much do you need to accomplish your goal & objectives?

What are the budget items? (personnel, fringe benefits, equipment, space, consultants, etc.)

1.

2.

3.

4.

5.

6.

7.

8.

What costs will you contribute?

How much does your institution charge (indirect costs)?

Task 1	Project Man. Plan	PI (UMB)	Year 1-Budget Period 1 Q1	Q2	Q3	Q4	Year 2-Budget Period 2 Q1	Q2	Q3	Q4	Year 3-Budget Period 3 Q1	Q2	Q3	Q4	Budget	Item
PHASE 1	Task 2	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
	Subtask 2.1	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
		Collaborator													500	Travel
	Task 3	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
	Subtask 3.1	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
		Collaborator													500	Travel
	Task 4	PI (UMB)													1,000	Materials & Supplies Equipment Travel
		Postdoc (UMB)														
		Grad (UMB)													5,000	
		Collaborator													500	
PHASE 2	Task 5	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
	Subtask 5.1	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
		Collaborator													500	Travel
	Task 6	PI (UMB)													1,000	Materials & Supplies
		Postdoc (UMB)														
		Grad (UMB)														
	Task 7	PI (UMB)													1,000	Materials & Supplies Travel
		Grad (UMB)														
		Collaborator													500	
		PI (UMB)		10,000				10,000				10,000			**30,000**	Salary-Fed. only, includ-ing fringe
		Postdoc (UMB)		40,000				40,000							**80,000**	
		Grad (UMB)		10,000				10,000				25,000			**45,000**	
		Undergrad (UMB)		6,000				6,000				6,000			**18,000**	
		Publications		2,000				2,000				2,000			**6,000**	
		Travel (Conferences)		5,000				5,000				5,000			**15,000**	
		Indirect Costs		20,000				20,000				15,000			**55,000**	
		Total Federal Costs													**266,000**	